

**AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs**

Minutes of the meeting held on
Thursday 13th October 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
Dr Neil Bugg	NBu	Birmingham Children's Hospital NHS FT
Dr Sangeeta Ambegaokar	SA	Birmingham Children's Hospital NHS FT
Mark DasGupta	MD	Birmingham CrossCity CCG
Satnaam Singh Nandra	SSN	Birmingham CrossCity CCG
David Harris	DH	Birmingham Community Healthcare NHS FT
Alima Batchelor	AB	Birmingham South Central CCG
Dr Waris Ahmad	WA	Birmingham South Central CCG
Jeff Aston	JA	Birmingham Women's Hospital
Nigel Barnes	NBa	BSMHFT
Tania Carruthers	TC	HoE NHS FT
Dr Timothy Priest	TP	HoE NHS FT
Carol Evans	CE	HoE NHS FT/ Solihull CCG
Kalpesh Patel	KP	Midlands & Lancashire CSU
Jonathan Horgan	JH	Midlands & Lancashire CSU
Isabelle Hipkiss	IH	Midlands & Lancashire CSU
Elizabeth Walker	EW	Sandwell & West Birmingham CCG
Kate Arnold	KA	Solihull CCG
Maureen Milligan	MM	The Royal Orthopaedic NHST
Inderjit Singh	IS	UHB NHS FT

IN ATTENDANCE:

Mrs Andrea Richards	AR	Dental Services, BCHC for item 1016/05
Mrs Harriet Anstey	HA	Birmingham Dental Hospital, for item 1016/05
Dr Shrikanth Pathmakanthan	SP	UHB NHS FT for item 1016/06
Dr Mujahid Saeed	MS	UHB NHS FT for item 1016/07
Claire Manzotti	CM	Midlands and Lancashire CSU

No.	Item	Action
1016/01	Apologies for absence were received from: <ul style="list-style-type: none"> • Prof Robin Ferner (Sandwell & West Birmingham Hospitals NHST) • Dr John Wilkinson (Solihull CCG) • Peter Cooke (Sandwell & West Birmingham Hospitals NHST) • Prof Jamie Coleman (UHB NHS FT) 	
1016/02	Items of business not on agenda (to be discussed under AOB) <ul style="list-style-type: none"> • Antimicrobial dressings algorithm • Decline to prescribe form • Update on Esmya[®] appeal 	
1016/03	Declaration of Interest (DoI) <p>It was confirmed that DoI forms have been received for all the guest clinicians attending the meeting.</p>	
1016/04	Welcome and Introductions <p>The chair welcomed everyone to the meeting today. Introductions were carried out for the benefit of the clinicians attending the meeting.</p> <p>The chair reminded members, that the meeting is digitally recorded for the purpose of accurate minute taking and once the minutes are approved, the recording is deleted by the APC secretary.</p>	
1016/05	Dental formulary review – Mrs Harriet Anstey (Consultant in Oral Surgery, Birmingham Dental Hospital) and Mrs Andrea Richards (Consultant in Oral Medicine, Dental services, BCHC) <p>The chair welcomed Mrs Richards and Mrs Anstey to the meeting. The draft dental formulary has been previously circulated for a 6 week consultation period.</p> <p><u>Discussion points/concerns regarding the draft dental formulary with proposed RAG rating:</u></p> <ul style="list-style-type: none"> • A member asked what process had been followed to prepare the proposed dental formulary. Members were informed the draft formulary was consolidated based on drugs used by the dental hospital and the dental services for many years. Drugs have been considered by the Drug and Therapeutics Committee at the Dental Hospital and medicines management group within BCHC. • A member queried whether clinical effectiveness and cost-effectiveness were assessed during this review process. It was confirmed these drugs are being used by the consultants at the Dental Hospital, closely linked to the School of Dentistry, and there is evidence of clinical effectiveness for these treatments. The cost of individual products was not included in the proposed dental formulary. It was emphasised that the Dental Hospital has its own budget as a speciality within the Trust, and can decide what drugs they use as long as the expenditure remains within budget. • Several members pointed out that the proposed RAG ratings in the draft dental formulary are different to the RAG ratings in the current APC formulary. For example, dosulepin for facial pain is proposed as green in 	

the draft dental formulary whereas it is black (non-formulary) in the APC formulary due to concerns over its safety. NICE and MHRA recommend that use in new patients should be avoided. The specialists stated that there is evidence in the dental literature that some antidepressants are better than amitriptyline for atypical facial pain, with a better side effect profile.

- Botulinum toxin is black in the APC formulary and red for masseteric hypertrophy in the proposed dental formulary. It was verified that Botulinum toxin is provided as part of tariff activities; there is no cost to the CCG.
- In response to a member pointing out that Buccolam® (buccal midazolam) is not licensed for pre-medication sedation; clinicians clarified that midazolam oral liquid is used and not Buccolam®, this error will be corrected.
- It was noted that the proposed dental formulary was split into two sections; first section listing drugs used by dental clinicians that are not in the APC formulary and the second section lists drugs that are included in the APC formulary but used by the dental clinicians for unlicensed/off-label indications.
- Several members highlighted that many drugs with a green RAG rating in the draft dental formulary involved off-label (unlicensed) use for the condition specified. E.g. pentoxifylline is not licensed for recurrent aphthous stomatitis or osteonecrosis of the jaw.
- It was emphasised that the APC green RAG rating applies to drugs that are suitable for GPs to initiate in primary care, but it was established that this was not the case for the drugs with a suggested green RAG rating in the dental formulary. If the drug is initiated by a specialist and then prescribing responsibility is transferred to primary care or the specialist recommends the drug is prescribed by primary care; this equates to an amber RAG status. If the recommended drug is used off-licence, the GPs will require additional information from the specialist to support prescribing in primary care (e.g. how long the course is for etc.). Clinicians stated that they provide the information in the clinical letter.
- The specialists reported that some GPs do prescribe off-label treatment for inflammatory conditions in the mouth. A member commented that a GP would not be prepared to prescribe beclometasone inhaler based on the recommendation of the dental specialist without additional information to support the prescribing. It was reiterated that GP needs to be aware that the drug recommended is used off-label. Clinicians added that very few steroids are licensed for buccal use and that hydrocortisone mucoadhesive buccal tablets are not very effective for treating severe ulcerative conditions. Use of some steroid formulations off-label is well established in dental practice to treat severe inflammatory ulcerative conditions.
- It was pointed out that during chapter 12 harmonisation, the APC members had taken advice from palliative care and oral medicine specialists to decide on the saliva substitutes to be accepted onto the formulary for ACBS approved conditions/ palliative care and Dental practitioners. These were Biotène Oralbalance® gel, Salivix® pastilles, Saliveze® oral spray and pilocarpine tablets. However the draft dental formulary did not include these, and proposed other products currently non-formulary. A member also commented that the evidence on efficacy for use of saliva stimulating tablets in patients with pharyngeal cancer is only anecdotal.
- A GP member advised that Medical Protection Society (MPS) and Medical Defence Union (MDU) advise GPs against prescribing for dental problems as the prescribing would be out of their remit.
- It was clarified that cyclizine is red in the draft dental formulary for nausea

- and vomiting because the injection is used rather than the tablets.
- A member stated that the proposed RAG rating for products used to treat neuropathic pain is different in the APC formulary. All anticonvulsants except carbamazepine and oxcarbazepine which are recommended for treatment of trigeminal neuralgia; are not effective in treating neuropathic pain. Both NICE and Cochrane conclude that there is low level of evidence to support using anticonvulsants (e.g. lamotrigine, sodium valproate) etc. in the treatment neuropathic pain.

Decision Summary:

The chair concluded that, based on the discussions at this meeting, the APC is unable to approve the draft dental formulary and the committee should re-consider a revised version at a later date.

Clinicians were asked to consider the following points when reviewing:

- RAG rating of drugs to be in line with APC definitions.
- Consider the need for shared care documentation; a generic RICaD may be required for drugs when used off-label.
- It was suggested that a table comparing the RAG ratings in the APC formulary with the proposed rating in the dental formulary would be useful. It was accepted that a drug may have a different RAG status for dental use.
- List of drugs consolidated from previous formularies; remove drugs no longer appropriate for the conditions specified.
- Evidence to support off-label use.
- Cost-effectiveness of drugs to be included in the draft dental formulary.

Actions: BCHC dental team to re-submit a revised draft formulary, taking into consideration the points raised

BCHC

1016/06 **New Drug application - Budesonide MMX (Cortiment®) – Dr Shrikanth Pathmakanthan (Consultant Gastroenterologist, UHB NHS FT)**

It was confirmed there were no Declarations of Interests for Ferring Pharmaceuticals Ltd.

The chair welcomed Dr Pathmakanthan to the meeting and invited him to present the new drug application for budesonide MMX.

Dr Pathmakanthan stated that oral steroids are the most widely used treatment for inflammatory bowel conditions because they are very efficacious and work well most of the time. However there are numerous side effects are associated with oral steroids and can be particularly debilitating for certain groups of patients (female and pregnant patients).

For Ulcerative Colitis patients it is beneficial to deliver more of the drug where it matters in the large bowel, mainly colon. Budesonide MMX tablet is coated with a resin to protect it against acid on its way through the stomach and small intestine. The resin is a hydrophilic matrix gel that will disintegrate in the colon when it reaches PH7 and coat the colon with steroids.

It has been used in 4 patients under DTC chairman's action.

Budesonide MMX is beneficial:

- In pregnant patients who cannot tolerate strong side effects with recurrent

doses of oral steroids.

- In keeping patients out of hospital – it avoids the need for intravenous steroids. Administration of intravenous steroids is associated with a 3-5 day stay in hospital (2 to 3 days for intravenous administration and then conversion from intravenous to oral route before discharge).
- Option for patients who would otherwise suffer from severe side effects with oral steroids.
- Avoids the need to move onto stronger immunomodulating drugs with the accompanying problems associated with these drugs. However immunomodulating drugs are very effective.

It costs £150 for an 8 week course, one 9mg tablet daily.

Dr Pathmakanthan indicated that he was requesting approval for prescribing by consultants and nurse specialists only.

The chair invited questions and comments from members. Discussion points/concerns raised included:

- A member asked if there had been any change in evidence since NICE published their evidence summary just over a year ago when it concluded that effect size was small; clinical relevance of improvement was unclear; and there was no statistically significant difference between budesonide MMX and placebo. The specialist stated that the two CORE trials (CORE I and CORE II) had demonstrated that budesonide MMX was significantly better in terms of clinical symptoms and mucosal healing than placebo. Budesonide MMX would not be compared to oral steroids. Treatment with budesonide MMX will show equivalence but not superiority to oral steroids. Thousands of patients would be required to show that little bit of incremental superiority over oral prednisolone. Therefore trials for many oral aminosalicylates use placebo as a comparator.
- It was highlighted that the side effect profile for oral and intravenous steroids is different. In some patients the significant side effects of oral steroid treatment may outweigh the benefits.
- Oral budesonide is available in two strengths (3mg and 9mg) but only the 9mg Cortiment® has the MMX matrix coating delivering the drug in the colon. The other two formulations of slow-release budesonide (Entocort®CR and Budenofalk®) are designed to release the steroid further down the terminal ileum and are mainly used for small bowel Crohn's disease (different indications), as well as a niche treatment for collagenous microscopic colitis.
- Following a resubmission, the Scottish Medicines Consortium has accepted budesonide MMX for restricted use in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where aminosalicylate (5-ASA) treatment is not sufficient (published 10th October 2016). The SMC restriction: for use in patients with UC who present with active left-sided disease and/or proctosigmoiditis who are not suitable for oral prednisolone, as an alternative to budesonide rectal formulations or off-label oral budesonide.
- The specialist clarified that first line treatment is maximising symptom control with aminosalicylates; second line is oral steroids; third line intravenous steroids; fourth line steroid sparing immunomodulators; fifth line biological therapy and sixth line surgery. The suggested place of budesonide MMX is before intravenous steroids avoiding hospital

admissions. Only one or two patients would be treated with this agent per month.

- It was emphasised that Budesonide MMX will never replace oral prednisolone. Oral Prednisone is very efficacious and all patients will be trialled with oral prednisolone. Budesonide would only be used in patients with severe side effects with oral prednisolone such as cushingoid features, severe acne or raging temper.
- Ulcerative colitis tends to worsens in one third of the pregnant women; budesonide MMX is useful, particularly during the middle of their pregnancy as it is difficult to use higher doses of oral steroids. Side effects are lower due to higher first pass metabolism through the liver, and constitutionally the patients will feel better as most of the drug remains in the colon.
- It was noted that in the application proposed an amber RAG rating, which contradicts the opening statement of consultant and specialist nurse prescribing only. The specialist clarified that budesonide would be initiated in secondary care with two weeks supply and then GP will be expected to prescribe for the remaining 6 weeks only.
- It was suggested that a RICaD would be required if the drug was approved as amber.

The chair thanked Dr Pathmakanthan for his presentation and advised him that the decision would be relayed within 7 days, in line with APC policy.

Further discussion points raised in the absence of Dr Pathmakanthan included:

- It was noted that both the SMC and SPC recommend that when treatment is discontinued, a gradual reduction of the dose may be useful at the discretion of the clinician.
- It was concurred that UHB will report back in 12 months with case reports for 20 patients. Data required will include:
 - How many admissions have been avoided? (patients were prescribed budesonide MMX who would have otherwise received intravenous steroids).
 - How many patients ended up receiving intravenous steroids?
 - How many patients have received intravenous steroids previously?
 - How many patients ended up with surgery?
 - Track patient journey
- It was pointed out that the green box on the algorithm needs amending as it currently places oral prednisolone and Budesonide MMX at the same position in the treatment pathway.

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

Patient Safety: Trial data shows that the incidence of adverse events was similar with budesonide and placebo. Budesonide has a similar safety profile to other oral steroids, but anecdotal evidence suggests it is better tolerated.

Clinical effectiveness: In two 8-week studies, budesonide MMX statistically significantly increased rates of combined clinical and endoscopic remission in adults with mild to moderate ulcerative colitis compared with placebo. However the effect size was small and the clinical relevance of the improvements is unclear. There was no statistically significant difference between budesonide MMX and placebo for clinical improvement and endoscopic improvement at week 8 (secondary end points).

Strength of evidence: No evidence comparing to active treatment. Small clinical trials.

Cost-effectiveness or resource impact: SMC concluded the economic case has been demonstrated. Suggestion made that this could avoid hospital admission for IV steroids, but no data as yet. More expensive than oral prednisolone.

Place of therapy relative to available treatments: Second line after failed trial of oral prednisolone, to avoid use of IV steroids.

National guidance and priorities: No MTRAC, NICE TA.
October 2016: SMC accepted for restricted use within NHS Scotland.

Local health priorities: Need data as to whether hospital admissions are prevented.

Equity of access: N/A

Stakeholder views: N/A.

Implementation requirements: N/A

Decision Summary: RED Initiation and maintenance of prescribing by Specialists only.

Rationale: As yet little information to confirm admissions would be avoided. The APC would wish to see this data in the form of case reports, tracking the patients' journey. Would also require further clarification around discontinuation as the SmPC recommends it may be useful to gradually reduce the dose at the discretion of the treating physician. Review in 12 months.

Actions:

- Relay decision to Dr Pathmakanthan by Thursday 20th October 2016.
- Add Cortiment® to APC formulary as RED status.
- UHB clinicians to present evidence on admission avoidance in form of case reports to APC in November 2017. Cohort of patients to include those with previous admissions for IV steroids.
- Require further clarification on GP actions when discontinuing.

APC sec
APC sec
UHB

UHB

1016/07 New Drug application – Dulaglutide (Trulicity®) – Dr Mujahid Saeed (Consultant Diabetologist, UHB NHS FT)

The chair welcomed Dr Saeed to the meeting and invited him to present the new drug application for dulaglutide (Trulicity®).

Dr Saeed and MD both declared they have attended an advisory board regarding Trulicity® for Eli Lilly and company Ltd. in the past.

Dr Saeed explained that Trulicity® has been considered by the Diabetes Medicines Management Advisory Group (DMMAG) which includes colleagues from primary care and the Trusts (clinical service leads and pharmacy representatives), then UHB's MMAG prior to approaching the APC.

Glucagon-like peptide 1 receptor (GLP-1) agonists improve glycaemic control by:

- Reduction in weight by increasing satiety and slowing down gastric emptying, which results in decreased calorie and carbohydrate intake.

- They work on beta cells to promote insulin release.
- Glucagon is reduced which reduces blood sugars post prandially.
- Only works with hyperglycaemia.

There is a lot of experience with the plethora for GLP-1s available since 2007. The other four GLP-1s are green on the APC formulary.

There are single NICE Technology Appraisals for some individual GLP-1s but the Management of Type 2 Diabetes in adults guideline (NG28) published in December 2015 do not specify any particular GLP-1, but deals with them at class-level.

Six phase-3 head to head studies involving 5000 patients compared dulaglutide add-on therapy against DPP-4 inhibitors (sitagliptin), GLP-1 agonists (exenatide twice daily and liraglutide once daily), insulin in basal bolus regimen (rapid acting and long acting insulin). These clinical trials also evaluated dulaglutide monotherapy against metformin.

In term of clinical efficacy (HbA_{1c} reduction) dulaglutide 1.5mg add-on therapy was superior to the active comparator, with exception of liraglutide at 1.8mg where it was non-inferior (NB: liraglutide usual prescribed dose is 1.2mg). Dulaglutide 0.75mg (dose used for monotherapy or patients over 75 years) was superior to metformin.

Weight reduction is superior with dulaglutide 1.5mg compared to liraglutide 1.2mg but not superior when compared to higher dose (1.8mg liraglutide) by a margin of 0.7kg.

In terms of safety profile, there are no new concerns. Gastrointestinal side effects are common due to slowing of gastric emptying. Incidences of symptomatic hypoglycaemia was common ($\geq 1/100$) when dulaglutide was used as monotherapy or in combination with agents that do not predispose to hypoglycaemia, and very common (≥ 1 in 10 patients) when used in combination with agents that predispose to hypoglycaemia.

A meta-analysis of previous studies has not shown any increased risk of cardiovascular side effects.

Dulaglutide is a once weekly formulation whereas other GLP-1s are once a day or twice daily.

Dr Saeed demonstrated that Bydureon® pens (exenatide prolonged release) needs re-constitution involving turning a dial, taping the pen 80 times and then turning the dial again before injecting. In comparison the Trulicity® device is a ready to use pen which incorporates a hidden needle which automatically retracts following dose delivery (i.e. should help minimise sharps injuries), and may be beneficial for patients with needle phobia as it has a hidden smaller needle. Therefore compliance with dulaglutide would be better as it is easier to use. No need for dose escalation that is required with Victoza® (liraglutide, dose scale from 1.2mg to 1.8mg - average national dose is 1.5mg).

Dulaglutide does not need any dose adjustments in renal impairment; it can be used to eGFR down to 30mL/min.

Patients would benefit with once weekly injections compared to twice daily exenatide or once daily liraglutide.

Can be used as add on therapy or monotherapy. Can be combined with any insulin whereas other GLP-1 can only be used with basal insulin only.

Top four GLP-1s are Trulicity®; Victoza® (1.2mg); Bydureon® and Byetta®.

Dulaglutide is cost neutral.

Once weekly to once weekly comparison; no added cost.

Based on evidence expect 1% reduction in HbA_{1c} and 3% weight loss after 6 months treatment.

Dr Saeed added that if the formulary was to be rationalised exenatide twice daily could be removed as it not used that often.

Dr Saeed concluded his presentation by recapping the benefits of dulaglutide based on patient outcomes:

- Safety – comparable to other GLP-1s; patients are put off by large needle in Bydureon® pen
- Efficacious
- Cost-effective – no additional cost
- Broader license (renal use and use with all insulins)
- Easy to use device; once weekly formulation, no need to reconstitute.

The chair invited questions and comments from members. Discussion points/concerns raised included:

- A member asked if there was any research comparing the different injection devices. It was established there are no studies comparing the different pen devices but based on the differences in the pen devices it can be deduced that dulaglutide is easier to use. Needle needs to be added to liraglutide pen and Bydureon® pen requires reconstitution.
- A member proposed that a once weekly formulation is likely to confuse patients particularly in elderly patients as they have all their other medicines daily. It was noted that there is 72 hour window in which a patient can take dulaglutide injection. Based on UHB data (2015) 1 in 9 patients prefer weekly doses.
- It was agreed that dulaglutide monotherapy is not cost-effective compared to metformin but can be an option for patients if they are intolerant to metformin.
- Although dulaglutide with insulin is licensed it is not cost-effective compared to lixisenatide plus insulin. Dr Saeed responded that lixisenatide will require increasing insulin doses to obtain benefit. Based on 2015 UHB data, small number of patients were prescribed lixisenatide. In addition there is cost associated with basal bolus regimens and increasing insulin doses. He added that evidence from the 20 year UKPDS study demonstrates metabolic benefits.
- It was reported that patients may increase their dose of liraglutide from 1.2mg to 1.8mg as the pen device allows them to do so; resulting in increased hidden costs. In contrast dulaglutide is available as a fixed dose pen.

The chair thanked Dr Saeed for his presentation and advised him that the decision would be relayed to him within 7 days, in line with APC policy.

Further discussion points raised in the absence of Dr Saeed included:

- It was emphasised the DMMAG had agreed that only lixisenatide should be used in combination with insulin. Rationale for GLP-1 in combination was not HbA_{1c} control and weight reduction but reduction in insulin dose.
- It was concurred that pen devices have not been compared directly with each other; therefore reports of ease of use are anecdotal.
- There was some debate on once weekly versus daily dosage.

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

Patient Safety: Not significantly different to other GLP-1 agents, but no dosage adjustment is required in patients with mild or moderate renal impairment.

Clinical effectiveness: equivalent to other licensed GLP-1s at licensed doses – possibly better tolerated in terms of delivery device.

Strength of evidence: Strong evidence

Cost-effectiveness or resource impact: Cost-neutral

Place of therapy relative to available treatments: Equal with other GLP-1s.

National guidance and priorities: NICE TA for other GLP-1s. NICE guideline 28 (Type 2 diabetes in adults: Management) covers use of GLP-1 as a class.

Local health priorities: Not as monotherapy as more cost-effective options are available

Not in combination with insulin – local agreement with DMMAG that only lixisenatide should be used in combination with insulin. Role of GLP-1 is to reduce insulin doses.

Equity of access: N/A

Stakeholder views: N/A.

Implementation requirements: None

Decision Summary: GREEN – Not as monotherapy; Not in combination with insulin

Actions:

- Relay decision to Dr Saeed by Thursday 20th October 2016. **APC sec**
- Add Trulicity® to APC formulary as GREEN status with the annotation ‘Not as monotherapy’ and ‘Not in combination with insulin’. **APC sec**

1016/08 Minutes of the meeting held on Thursday 8th September 2016

The minutes of the meeting held on Thursday 8th September 2016 were accepted as an accurate record and approved with no amendments. They can be uploaded to the APC website and the recording deleted.

The following documents were also approved:

- DST Dymista®
- Amended Allergic Rhinitis pathway
- DST Guanfacine Prolonged release
- Revised Methotrexate ESCA for Rheumatoid Arthritis and psoriatic arthritis

Discussion points included:

- At last APC meeting it was decided to amend the methotrexate injection to Metoject® on the formulary due to safety concerns and Metoject® being a patient friendly injection device. The Rheumatoid Arthritis team have confirmed they have no issues. But the Gastroenterology team have reported that the evidence for intramuscular methotrexate is better than

subcutaneous or oral methotrexate. Metoject® is only licensed for subcutaneous route. It was established that intramuscular route was unlicensed with the generic methotrexate presentation as well. It was agreed that the GI Team should be approached to review the ESCA for Crohn's disease.

- When the Dermatology section was reviewed it was proposed that the methotrexate ESCA for rheumatology should be extended to include use in dermatology. Members agreed it was acceptable to include dermatology use in the rheumatology document provided the dose; frequency and monitoring are the same.

Action: Review Methotrexate ESCA for rheumatology to include dermatology use.

**APC sec
Dermatology
Team**

1016/09 Matters arising – Action Table

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

(see separate document attachment for updated version – only actions that are not closed were discussed)

- 0916/11 – Amend APC policy in relation to abbreviated application form
Update: Outstanding
- 0916/13 – NICE Technology Appraisal Degarelix: CCGs to explore access to discounted price and a solution for prescribing and administration of degarelix in primary care.
Update: Discounted prices available to CCGs - CLOSED
- 0716/08 – Practicalities of ESCAs and RICaDs: Individual Trusts to work with their internal IT department to find a solution. Share solutions with other trusts.
Update: BSMHFT reported it is a problem. Ongoing
- 0716/11 – Draft ESCA for enoxaparin for consultation.
Update: Outstanding
- 0716/11 – HEFT to put forward an application via a formal letter requesting change of RAG status for enoxaparin
Update: Outstanding
- 0516/10 – Awaiting 'decline to prescribe' from SWBH
Update: Outstanding
- 1115/12 – SWBH to liaise with renal team, on iron dextran injection (CosmoFer®) to clarify RAG status and need for supplementary documentation.
Update: Outstanding

1016/10 Patient and Public Representative – Merits and challenges

Discussion points regarding Patient and Public representative included:

- Numerous attempts to recruit lay member have proved unsuccessful.
- It was added that each organisation has links with non-executive directors or unpaid governors. CCG's have lay advisors. It was proposed these individuals are approached as they have already demonstrated a commitment to the NHS.
- It was suggested that this is put on hold until the RMOC Terms of Reference are available, expected around February 2017. If the role of this committee is implementer then a lay member is not necessary.

However if the role of this committee is decision maker then a lay member is required.

Actions: Await RMOG Terms of Reference to ascertain role of committee before going forward with recruitment of patient and public representative. **Joint chairs**

1016/11 **Simbrinza® - additional information provided by Dr Pandey**

Members were reminded that when the Simbrinza® drug application was considered in June 2016, the decision was deferred pending additional information from Mr Pandey by answering three questions from the members.

The first question was evidence that one drop is better than two drops. Clear evidence has been provided.

Question two was requesting an algorithm for treating glaucoma (what is first line; second line; third line) and question three was asking for approximate number of patients at each step of the algorithm.

Mr Pandey answered questions 2 & 3 together (including numbers at each stage):

- 1st line Prostaglandin analogue (2502 patients)
- 2nd line beta-blocker (489 patients); Prostaglandin analogue plus Beta Blocker (320 patients)
Carbonic anhydrase inhibitor (890 patients)
- 3rd line Alpha agonist (926 patients)
- Simbrinza® (alpha agonist and Carbonic anhydrase inhibitor combination (55 patients)

It was acknowledged that Mr Pandey had responded to the member's questions adequately and Simbrinza® was accepted on the formulary as AMBER (specialist recommendation).

Action:

- Relay decision to Mr Pandey by Thursday 20th October 2016.
- Add Simbrinza® to APC formulary as AMBER with the annotation third line.

APC sec
APC sec

1016/12 **NICE Technology Appraisal (TAs)**

There were 7 NICE Technology Appraisals published in September 2016 (one negative; four commissioned by NHSE and two commissioned by CCGs).

- TA409 Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion – commissioned by CCG but providers are NHS hospital trusts and private providers. Agreed RED status on formulary.
- TA407 Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors – commissioned by CCGs and providers are NHS hospital trusts. Agreed RED status on formulary.

- TA404 Degarelix for treating advanced hormone dependent prostate cancer was revisited. It was confirmed that degarelix is available to CCGs at same discounted drug costs as that available to the Trusts via the Patient Access Scheme. Agreed AMBER with a RICaD in the formulary.

Actions:

- Update APC formulary with decisions on NICE TAs
 - Develop and circulate draft RICaD for degarelix with members for consultation.
- APC sec
SSN/ APC sec**

1016/13 Trust Chairs non-Formulary approvals

UHB NHS FT document was circulated for information only.

Any Other Business :

1. Decline to prescribe forms – request to add tick boxes and names of CCG by GP signature to facilitate Trusts to identify relevant CCG leads to contact if necessary. Revised form was accepted.

ACTIONS:

- **Add name of CCG field to the decline to prescribe form.**
 - **circulate revised form and upload to APC website**
- APC sec
APC sec**

2. Esmya® Appeal – Members were reminded that Miss Pradhan was previously offered the option of going forward with the appeal in November 2016 with Dudley APC and the BSSE APC would consider the appeal outcome at the December APC meeting. Alternatively BSSE APC will reconsider the application at the December meeting.

However, Dudley APC's view was that given there are now clear NICE guidelines positioning Esmya®, there is little value in their committee spending time reviewing the original submission.

Consequently it was agreed the APC members will reconsider the application at the December APC meeting, having had time to review the NICE clinical guideline and the evidence underpinning it. The members will review the clinical aspect but the likelihood is that, based on the figures put forward by the clinician (number of patients and number of cycles per patient), the cost would exceed the delegated authority that CCGs have. If it were approved on the basis of the NICE understanding of the evidence, it may still need to go forward for a commissioning decision.

Miss Pradhan should be informed that her application will be reviewed in line with the recently published NICE guidance at the December APC meeting; she does not need to re-submit an application nor does she need to attend the meeting. Following APC's review in December, Miss Pradhan will be informed the decision. If the cost impact exceeds the CCGs' delegated authority, she will be advised it is a commissioning decision and will require service redesign.

ACTION: Inform Miss Pradhan that committee will reconsider her application at December meeting in light of NICE guidance being published. Miss Pradhan does not need to re-submit her application nor does she need to attend the meeting.

APC Sec

3. Antimicrobial dressings algorithm – It was outlined that at the September Away day, changes to the Antimicrobial dressings algorithm were discussed and that these would be presented to the full committee for approval. Further changes to the algorithm were proposed:
 - a. Swap the first two boxes on the left hand side. ‘At every stage of wound examination, look for systemic features of sepsis’ should be the first box and ‘Do you think the wound is infected?’ should be the second box.
 - b. Fifth box on the left hand side of algorithm – Amend the first sentence to read ‘Stop second antimicrobial dressings after a maximum of 2 weeks and return to non-antimicrobial dressing’ instead of ‘Stop antimicrobial dressings after a maximum of 4 weeks and return to non-antimicrobial dressing’. Amend the second sentence to read ‘If there has been no improvement, consider co-morbidities and non-infectious causes.’ instead of ‘If there is no improvement, consider co-morbidities and non-infectious causes before using further antimicrobial dressings.’

It was agreed that subject to further amendments outlined above, the algorithm was approved.

Members were updated that the wound care group meeting on Monday 17th October will be reviewing the RAG ratings and rationalisation following discussions at the away day.

ACTION: Amend the Antimicrobial dressings algorithm as agreed

APC sec

The chair thanked the members for their input today. The meeting closed at 16:50 pm.

Date of next meeting: Thursday 10th November 2016 14:00 – 16:45
Conference Room A,
Birmingham Research Park,
Vincent Drive.
Birmingham B15 2SQ