AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 8th December 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 Sangeeta Ambegaokar	SA	Birmingham Children's Hospital NHS FT
Mark DasGupta	MD	Birmingham CrossCity CCG
Dr Waris Ahmad	WA	Birmingham South Central CCG
Alima Batchelor	AB	Birmingham South Central CCG
Jeff Aston	JA	Birmingham Women's NHS FT
Tania Carruthers	TC	HoE NHS FT
Dr Timothy Priest	TP	HoE NHS FT
Carol Evans	CE	HoE NHS FT/ Solihull CCG
Ravinder Kalkat	RK	Midlands & Lancashire CSU
Jonathan Horgan	JH	Midlands & Lancashire CSU
Isabelle Hipkiss	IH	Midlands & Lancashire CSU
Kate Arnold	KA	Solihull CCG
Dr John Wilkinson	JW	Solihull CCG
Prof Jamie Coleman	JC	UHB NHS FT
Inderjit Singh	IS	UHB NHS FT
Christopher Anton	CA	SWB Hospitals NHST

IN ATTENDANCE:

George Wilde	UHB NHS FT (observer)

No.	Item	Action

1216/01 **Apologies for absence were received from:**

- Prof. Robin Ferner SWB Hospitals NHST (deputy attended)
- Peter Cooke SWB Hospitals NHST
- Dr Neil Bugg Birmingham Children's Hospital NHS FT
- David Harris Birmingham Community Healthcare NHS FT
- Satnaam Singh Nandra Birmingham CrossCity CCG
- Nigel Barnes BSMHFT
- Maureen Milligan The Royal Orthopaedic NHST

It was confirmed that the meeting was quorate.

1216/02 **Items of business not on agenda** (to be discussed under AOB)

- ESCAs- age range; ratification
- Pramipexole MR

1216/03 **Declaration of Interest (DoI)**

It was confirmed that DoI forms have been received for all members attending the meeting. A member declared interests relating to a couple of items on the agenda; these will be noted under the respective items.

1216/04 **Welcome and Introductions**

The chair welcomed everyone to the meeting today. Introductions were carried out for the benefit of new attendees.

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.

1216/05 **Abbreviated Drug application – Levetiracetam granules in sachets (Desitrend®)** – Desitin Pharma Ltd

A member declared receipt of honorarium from Desitin Pharma Ltd for attending an advisory board some time ago. It was established there were no other Declarations of Interests for Desitin Pharma Ltd.

As this is an application for a new formulation of a drug already on the APC formulary, the requesting clinician is not expected to attend. The chair therefore invited the APC secretary to summarise the abbreviated application form on behalf of Professor Rajat Gupta, Consultant Paediatric Neurologist, Birmingham Children's Hospital.

Currently the APC formulary lists levetiracetam generically and both tablets and sugar-free oral solution are accepted. The RAG status is AMBER.

Desitrend® is a relatively new formulation of levetiracetam and presents as coated granules (2mm in diameter) in sachets. It has the same licensed indications, and is available as 250mg, 500mg and 1000mg doses.

The advantages this product offers to the patient include:

- An alternative formulation for patients particularly children who may have difficulties with conventional formulations which may affect treatment

adherence.

- Current guidance suggests a maximum volume of liquid medication of 10mls for children up to the age of 10. Desitrend® would facilitate an earlier transition from liquids and the difficulties associated with them.
- Guidance also suggests a maximum tablet size of 10mm for children up to the age of 11 and 15mm for patients up to the age of 17. All conventional levetiracetam tablets exceed 10mm and both the 500mg and 1,000mg doses exceed 15mm long.
- The coated granules must be taken orally, swallowed with a sufficient quantity of liquid and may be taken with or without food.

The clinical advantages include:

- Improved efficacy and compliance.
- Desitrend® is the only form of levetiracetam licensed for administration via a PEG tube.
- It is also carbohydrate free and therefore suitable for patients on the ketogenic diet.

The applicant goes on to quote the financial advantages of Desitrend® over existing therapy is a 20% lower acquisition cost over the more widely used brand of levetiracetam (Keppra®).

The specific patient group for which the clinician anticipates the drug will be used was defined as:

- Any patients who have difficulties with conventional formulations especially children aged 6-16 for whom conventional tablets are larger than recommended maximum acceptable size.
- Any patients requiring the administration of levetiracetam via a PEG as Desitrend® is the only formulation of levetiracetam licensed for this route.
- Any patients on the ketogenic diet (requiring levetiracetam) as Desitrend® is carbohydrate free.

The applicant envisages prescribing for around 30 patients a year at BCH.

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

- The cost savings quoted by the applicant were based on a comparison with Keppra®; however levetiracetam is available as a generic at a fraction of the price. A year's supply at a dose of 500mg twice daily would cost:
    - £480 if prescribed as Desitrend®
    - £600 if prescribed a Keppra®
    - £33.58 if prescribed as generic levetiracetam tablets
    - £77 if prescribed as generic levetiracetam SF oral solution (100mg/ml)
- Levetiracetam is classed as Cat 3 by MHRA which means it is usually unnecessary to ensure that patients are maintained on a specific manufacturer's product unless there are specific reasons such as patient anxiety and risk of confusion or dosing errors.
- A member summarised the request as for patients with difficult compliance who need adjunctive therapy (as only licensed as adjunctive therapy in younger age group), or who cannot tolerate liquid formulation or on a ketogenic diet.
- It was pointed out that ketogenic diets are rarely used in adults or they rarely stay on them.

- The BCH representative reassured the members that this formulation would not be used first line but in a niche cohort of patients on multiple antiepileptic agents, who may be tube fed, as this offers an alternative formulation which would be more suitable for them.
- A member enquired about the carbohydrate content of the sugar free oral solution. It was pointed out however that it was not just the carbohydrate content of this preparation that was important but the overall carbohydrate load of the multiple medications the patient was taking, and that this offered an option to keep it low.
- HEFT and UHB confirmed that any patient transitioning to their Trusts under adult services would be reviewed and Desitrend® would be used if still deemed appropriate, but their clinician would not be initiating it.
- The members agreed to clarify the cohort of patients further: any patients up to and including 16 years of age unable to swallow tablets and in whom the liquid formulation is not appropriate or tolerated.

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

Patient Safety: Equivalent to tablets or liquid

Clinical effectiveness: Equivalent to tablets or liquid

Strength of evidence: Equivalent to tablets or liquid

Cost-effectiveness or resource impact: Substantially more expensive than generic tablets or liquid.

Place of therapy relative to available treatments: Second line, only if tablets or liquid formulation inappropriate

National guidance and priorities: N/A

Local health priorities: CCGs redefined patient cohort

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: None

Decision Summary: Accepted onto formulary as AMBER, paediatrician initiation. For patients up to and including 16 years of age unable to swallow tablets and in whom the liquid formulation is not appropriate or tolerated.

Actions:

APC sec
- Relay decision to Prof Gupta by Thursday 15th December 2016.

APC sec
- Add Desitrend® to APC formulary as AMBER, Paediatrician initiation. Clarify patient cohort as agreed

1216/06 Abbreviated Drug application – Sodium Valproate prolonged-release granules in capsules/sachets (Episenta®) – Desitin Pharma Ltd

A member declared receipt of honorarium from Desitin Pharma Ltd for attending an advisory board some time ago. It was established there were no other Declarations of Interests for Desitin Pharma Ltd.

As this is an application for a new formulation of a drug already on the APC

formulary, the requesting clinician is not expected to attend. The chair therefore invited the APC secretary to summarise the abbreviated application form on behalf of Professor Rajat Gupta, Consultant Paediatric Neurologist, Birmingham Children's Hospital.

Currently the APC formulary lists sodium valproate generically and the following formulations are listed: E/C tablets, M/R tablets, crushable tablets and SF liquid. The RAG status is AMBER.

Episenta® is a relatively new formulation of sodium valproate and presents as prolonged release granules (2mm in diameter) in capsules and sachets. It is licensed for all forms of epilepsy and for the treatment of manic episodes in bipolar disorder / mood stabiliser when lithium is not tolerated or contraindicated. It is available as 150mg and 300mg granules in capsules, 500mg and 1000mg granules in sachets.

The advantages this product offers to the patient are similar to those described under Desitrend®. Episenta® is also the only prolonged-release (once daily) formulation of sodium valproate licensed for bipolar disorder.

The clinical advantages include:

- Improved efficacy and compliance due to the once daily dosing of Episenta®
- It is also carbohydrate free and therefore suitable for patients on the ketogenic diet.

The financial advantages of Episenta® are quoted as it being the least expensive prolonged-release (once daily) preparation of sodium valproate, the least expensive form licensed for bipolar and also less expensive than most immediate –release (IR) formulations.

The proposed patient group for which this drug would be used is defined as:

- Any patients who have difficulties with conventional formulations especially children aged 6-16 for whom conventional tablets are larger than recommended maximum acceptable size.
- Any patients where adherence may be improved by a change of formulation or switch from twice daily to once daily treatment.
- Any patients starting sodium valproate unless there is sufficient patient benefit to justify a more expensive formulation.

The applicant envisages prescribing for around 50 patients a year at BCH.

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

- The costs quoted by the applicant in the cost comparison section are all accurate with the exception of sodium valproate enteric coated tablets as these would be prescribed generically and are much cheaper than Epilim®.
- Episenta® is indeed cheaper than all MR preparations.
- It was confirmed that Epilim® Chronospheres® (the closest formulation to Episenta®) is not on the formulary.
- Sodium valproate is classed as Category 2 by the MHRA which means the need for continued supply of a particular manufacturer's product should be based on clinical judgement and consultation with patient and/or carer, taking into account factors such as seizure frequency and treatment

history.

- It was confirmed that the granules can be sprinkled on cold soft food and swallowed without chewing; the granules can also be taken in a cold drink and the glass should be rinsed with a small amount of water which should be swallowed as well.
- A member summarised that this was an option for a once daily modified release preparation for those who find swallowing tablets difficult. It was suggested that sprinkling the granules on yogurt would improve compliance in children.
- A member commented that the opportunity of reducing the tablet burden for children with multiple co-morbidities would improve their quality of life as well as that of their families.
- It was agreed to redefine the patient cohort as: patients with epilepsy aged up to and including 16 years of age unable to swallow tablets who require a modified release formulation in whom other formulations are more expensive or not appropriate or tolerated.

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

Patient Safety: Equivalent to tablets or liquid

Clinical effectiveness: Equivalent to tablets or liquid; improved efficacy demonstrated due to improved compliance.

Strength of evidence: Equivalent to tablets or liquid

Cost-effectiveness or resource impact: Less expensive than all modified release formulations but more expensive than plain e.c. tablets.

Place of therapy relative to available treatments: alternative option for those unable to swallow tablets and who require modified release formulation

National guidance and priorities: N/A

Local health priorities: would support, cohort of patient redefined.

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: None

Decision Summary: Accepted onto formulary as AMBER, paediatrician initiation. For patients with epilepsy aged up to and including 16 years of age unable to swallow tablets and who require a modified release formulation in whom other formulations are more expensive or not appropriate.

Actions:

- Relay decision to Professor Gupta by Thursday 15th December 2016. **APC sec**
- Add Episenta® to APC formulary as AMBER Paediatrician initiation. Clarify patient cohort as agreed **APC sec**

1216/07 Abbreviated Drug application – Alendronate 70mg effervescent tablet (Binosto®) – Internis Pharmaceuticals Ltd

It was established there were no Declarations of Interests for Internis Pharmaceuticals Ltd.

As this is an application for a new formulation of a drug already on the APC formulary, the requesting clinician is not expected to attend. The chair therefore invited the APC secretary to summarise the abbreviated application form on behalf of Dr Karl Grindulis, Consultant Rheumatologist, SWBH NHS Trust.

Binosto® is an effervescent formulation of alendronate, with a buffer to reduce the additive effects of alendronic acid and gastric acid.
Alendronate is the first line bisphosphonate used in osteoporosis; there is an alternative weekly preparation risedronate and both are available as generic preparations.
Upper GI problems including inability to swallow alendronate and risedronate are the biggest problem in practice. This is not helped by the large number of generics which vary in size of tablet, some of which can be tolerated but not others and which are switched ad hoc by pharmacies.

There is a liquid alendronate formulation available but this is not well tolerated by patients due to the taste and the liquid contains a number of excipients.

The cohort of patients the clinician would like to use or recommend use of Binosto® was specified as patients who cannot tolerate alendronate or risedronate tablets or where there is a contraindication such as oesophageal dysfunction or Barrett's oesophagus.
The current alternative would be to move onto denosumab which requires 6 monthly sub-cutaneous injections. There is also an intravenous formulation of zoledronic acid which is another option for patients who cannot tolerate oral bisphosphonates but this is not suitable for many elderly patients due to the risk of prolonged flu-like reaction post-infusion, dose adjustments with regards to renal function, lack of data beyond three years and need for day unit facilities.

The cost of Binosto® is £22.80 for 4 weekly doses; this is similar to the cost of Fosamax® but substantially more expensive than generic alendronate or risedronate.
The costs of alternative treatment options are as follows (based on December 2016 Drug Tariff prices):
Alendronate 70mg tablets 78p for 4 doses
Risedronate 35mg tablets 89p for 4 doses
Alendronate liquid SF 70mg/100ml £27.36 for 4 doses
Denosumab £183 per 6 monthly dose.

The applicant indicated that the number of patients he would suggest this formulation to would not exceed 10-15 patients per year but realises that use in Primary care could potentially be much greater. This could however reduce hospital referrals because of the inability to swallow bisphosphonate tablets and possibly reduce the use of denosumab.
He also suggested a GREEN RAG status, in line with current formulary options.

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

- A member questioned the suggestion this would delay the move to denosumab as the next option as there are a number of criteria (namely T-scores, age and number of independent clinical risk factors for fracture) to meet before denosumab can be used.
- Primary care members were concerned about "creep" in prescribing for patients outside the identified cohort but agreed that it would be inappropriate to refer to secondary care if the outcome was likely to be a recommendation for Binosto®.
- Prescribing monitoring reports could include the new product to identify any significant increase in prescribing. Messages could also be added to Scriptswitch® to ensure appropriate use.
- A GP also questioned whether primary care clinicians would persevere with a bisphosphonate, albeit effervescent, if the patient had not tolerated either alendronate or risedronate tablets.
- The current formulary options are: alendronate (tablets and liquid) and risedronate (GREEN), ibandronic acid 150mg (AMBER), strontium ranelate (AMBER).
- It was agreed to define the place in therapy as: third line option after alendronate and risedronate.

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

Patient Safety: equivalent to other formulations of alendronate.

Clinical effectiveness: equivalent to other formulations of alendronate.

Strength of evidence: equal to other formulations of alendronate

Cost-effectiveness or resource impact: more expensive than tablet but less expensive than liquid formulation.

Place of therapy relative to available treatments: Third line option in individuals who have not tolerated first line alendronate tablets and second line risedronate tablets and in whom a bone-sparing agent is still considered clinically necessary.

National guidance and priorities: NICE TA

Local health priorities: CCGs are concerned about creep. Would require monitoring and Scriptswitch® messages.

Equity of access: N/A

Stakeholder views: N/A.

Implementation requirements: None

Decision Summary: GREEN £££ – Rationale: Third line option in individuals who have not tolerated first line alendronate tablets and second line risedronate tablets and in whom a bone-sparing agent is still considered clinically necessary.
Take liquid formulation off the formulary.

Actions:

- Relay decision to Dr Grindulis by Thursday 15th December 2016. **APC sec**
- Add Binosto® to APC formulary as GREEN £££status, and annotate with comments on place in therapy. **APC sec**
- Remove alendronate oral liquid from APC formulary. **APC sec**

1216/08 Esmya® (ulipristal acetate) drug application- reconsideration.

As this is a reconsideration of an application from March 2016 in light of an updated NICE guidance, the applicant was not expected to attend as agreed at the October 2016 meeting. The chair gave a brief summary of the process to date regarding this application. The APC secretary went on to summarise the main points on behalf of Miss Poonam Pradhan, Consultant in Obstetrics & Gynaecology, Heart of England NHS FT, and covered effectiveness, safety and patient factors.

With regards to effectiveness it was highlighted that the PEARL II study evaluated ulipristal against the active comparator GnRH analogue leuprorelin, and showed that ulipristal was non-inferior to monthly injections of leuprorelin acetate for controlling uterine bleeding.

Cost comparisons against GNRH analogues was discussed briefly:

Cost: For a three month course, excluding VAT,
Ulipristal orally 5mg daily £342
Goserelin 3.6mg s/c injection monthly £195
Leuprorelin 3.75mg s/c or IM injection monthly £226
Triptorelin 3mg IM injection monthly £207
Triptorelin 3.75mg s/c or IM injection monthly £245

Additional information provided by Miss Pradhan included:

- The maximum treatment time in the first year if using the minimum gap between courses would be 8 months which is in line with the Summary of Product Characteristics (3 months treatment / 2 months gap / 3 months treatment / 2 months gap / 2 months treatment, the 3rd month going into the following year) the cost would therefore be £913.04 per patient.

- Across HEFT, SWBH & the Women's approx. 200-250 women per year have received 1x3 month course of Esmya® pre-surgically (majority are late peri-menopausal age 45-50, plus those unsuitable/unwilling to undergo surgery) It was stated in the original application that the applicant would anticipate that:
  1. Approximately 15-20% of these women (mostly late peri-menopausal age 45-50) would be suitable for intermittent treatment i.e. 30 – 50 women would be eligible for intermittent treatment per annum across all trusts.
  2. This would equate to a maximum cost of £27,291 to £45,652 across all of Birmingham (£913.04 x 30 to £913.04 x 50).

- As stated in the original application, ulipristal acetate should be considered in a second line positioning where patients are unsuitable for, or have failed to respond to first line treatment of moderate to severe symptoms of uterine fibroids, thus invasive procedures are the relevant comparators. The comparative cost of existing treatment is:

a. Hysterectomy £3322
b. Myomectomy £3213
c. Uterine Artery Embolisation £2951 (National Tariff Costs)

- The key economic benefit from ulipristal acetate would be the avoidance of high upfront costs of invasive procedures for a proportion of patients.

- The gap between courses is not fixed and audits are showing that many women drop out of the system after 1 or 2 courses which suggest their symptoms are improved and manageable.

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

- The members can see the benefits of this treatment in late peri-menopausal women (45+) but were concerned that it would be used in a younger age group which could ultimately result in invasive surgery after incurring the costs of pharmaceutical treatment.
- It was reiterated that national bodies charged with reviewing best practice (SMC and NICE) have endorsed this product to be available as part of the options for NHS treatment.

- Feedback from a specialist at the Women's hospital stated that he would envisage using Esmya® in 2 scenarios:
    - In patients refractory to NICE recommended therapy and who want to preserve their fertility
    - In patients at too high risk for surgery (e.g. obesity or other co-morbidities).
    - Theses would account for 10-20 patients per year.
- Commissioners reminded the committee that this was NICE clinical guidance and not Technology Appraisal guidance (TAG), and therefore they are not obliged to fund it in the same way as a TAG. There are a number of clinical guidelines where commissioners are not currently in a position to implement some of the recommendations for a variety of reasons, often to do with finance but sometimes to do with capacity to deliver it. The committee needs to be careful about setting a precedent. The role of the committee in the overall process also needs to be considered carefully as it is not in its remit to redesign the service pathway which is what this requires if annual ultrasounds are to be taken into account.
- It was suggested that the committee members consider the pharmaceutical aspect i.e. is there evidence to support this use, but the decision on whether to commission it or not needs to be taken by the people charged with commissioning services and redesigning services. The funding needs to be in the right place to deliver the new model whereas currently it sits in the place to deliver the old model.

The members debated the need to complete the Decision Support Tool (DST) as it was felt the committee could stand by the comments noted in the original document, however the piece of evidence that swayed the decision was the revised NICE guideline ("Heavy menstrual bleeding: assessment and management, CG44, updated August 2016) which position Esmya® in the treatment pathway of women with heavy menstrual bleeding and fibroids of 3cm or more.
The members agreed to endorse the position that NICE has taken from an

APC perspective and now refer it back to the applicant and all Trusts wishing to use this agent to put forward a single case for change to the commissioners which can be considered along with other health priorities.

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

Patient Safety: As stated in NICE CG 44: Research is needed on the efficacy and safety of ulipristal acetate 5 mg over a period of more than 4 courses, compared with other uterus-sparing treatments.

Clinical effectiveness: As per NICE CG 44: The current evidence suggests that ulipristal acetate 5 mg is an effective treatment for women with heavy menstrual bleeding and fibroids of 3 cm or more in diameter. The evidence covers a period of 4 courses (20 months).

Strength of evidence: Sufficient to get licence extension and support from NICE in CG 44 and SMC. RCTs comparing to placebo and active comparator GnRH analogue leuprorelin, which showed ulipristal was non-inferior to monthly injections of leuprorelin and superior to placebo.

Cost-effectiveness or resource impact: Esmya® is approximately 17 times more expensive than tranexamic acid (monthly cost), 1.5 times more expensive than an average GnRH injection monthly cost, but less expensive than invasive surgical procedures.

Place of therapy relative to available treatments: In line with NICE CG 44.

National guidance and priorities: Revised NICE CG 44 on the management of Heavy Menstrual Bleeding published in August 2016. SMC has approved use 2nd line.

Local health priorities: Potential costs are high; therefore commissioners would invite all Trusts wishing to use this agent to put forward a single business case which can be considered along with other health priorities.

Equity of access: no issues

Stakeholder views: N/A

Implementation requirements: If commissioners agree to fund it, an ESCA would be required.

Decision summary: On the basis of NICE CG44, the APC would support the use of ulipristal acetate for intermittent use in line with licensed indication as AMBER with ESCA only if and when commissioners agree to fund it. Business case pending.

Actions:

- **Relay decision to Miss Pradhan by Thursday 15th December 2016.** **APC sec**

1216/09 Abbreviated Drug application – Sodium chloride 7% solution for inhalation – Resp-Ease® – Venture Healthcare Ltd.

It was established there were no Declarations of Interests for Venture Healthcare Ltd.

As this is an application for a more cost-effective brand of a drug already on the APC formulary, the requesting clinician is not expected to attend. It was clarified that the application was put forward by the Respiratory Directorate at Heart of England NHS Trust, not a consultant. The committee was satisfied that this was appropriate for this application.

The APC secretary stated that the current formulary entry for hypertonic saline solution 7% for inhalation recommended Nebusal® as the brand of choice. However Resp-Ease® which was recently launched is available at a lower acquisition cost: £21.60 for 60 vials compared to £27.00 for Nebusal®.
Resp-Ease® is also listed in the drug tariff.
The members agreed to replace the current formulary entry with Resp-Ease® 7%. The decision was solely based on the cost –effectiveness of the proposed replacement product. All other criteria are the same as the original product.

Decision: GREEN, to replace Nebusal®

Actions:

- **Relay decision to respiratory directorate by Thursday 15th December 2016.** **APC sec**
- **Add Resp-Ease® 7% to APC formulary as GREEN.** **APC sec**
- **Remove Nebusal® from APC formulary.** **APC sec**

1216/10 Minutes of the meeting held on Thursday 10th November 2016

The minutes of the meeting held on Thursday 10th November 2016 were discussed for accuracy.

Page 11: 1115/12: remove name of individual from SWB hospitals and replace with term “representative”

Page 13: remove name of Primary Care MI support. Remove name of clinician under insulin degludec, and replace with applicant.

It was confirmed that subject to the above amendments, the minutes are approved, can be uploaded to the APC website and the recording deleted.

The following documents were also approved:

- DST for midodrine
- DST for Epiduo® gel
- DST for Enstilar® cutaneous foam

1216/11 Matters arising – Action Table

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

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

- 1116/14 – AOB- Vitamin E- HEFT to check and confirm at the next APC meeting if Vitamin E suspension is suitable for prescribing in cystic fibrosis

patients. If yes remove Vitamin E capsules from the formulary.
Update: CF team has confirmed Vitamin E suspension is appropriate to use.
ACTION: **remove vitamin E capsules from APC formulary** **APC sec**

- 1116/14 – AOB- Vitamin E- Add products not listed in the Drug Tariff to the December APC meeting agenda
  Update: Defer to January 2017

- 1116/14 – AOB Vitamin E - Discuss at the next APC meeting the issue with some suppliers/dispensers charging inflated prices for products not listed in the drug tariff.
  Update: defer to January 2017

- 1116/14 – AOB Vitamin B12 - Joint Chairs to write to consultant haematologist asking him to clarify the misunderstanding following the training event. Outstanding

- 1016/08 – Review Methotrexate ESCA for rheumatology to include dermatology use.
  Update: Outstanding- Pharmacist from HEFT has offered to support.

- 1016/12 – Develop and circulate draft RICaD for degarelix with members for consultation.
  Update: First draft was circulated to Trust leads 24 November, with closing date for comments 8 December. Comments received from UHB clinicians imply an ESCA would be more appropriate as urologists would not discharge patients and discontinuation would be done by secondary care.
  ACTION: redraft as ESCA and circulate to APC members for consultation **SSN/APC sec**

- 0716/11 – Draft ESCA for enoxaparin for consultation.
  Update: First draft received by APC secretary 8 December, will be circulated for comments.

- 1115/12 – SWBH to liaise with renal team, on iron dextran injection (CosmoFer) to clarify RAG status and need for supplementary documentation.
  Update: SWBH has confirmed this will be removed from their formulary.

Letter from HoE FT to APC re enoxaparin:
The clinicians at HoE FT felt that writing a letter to the joint chairs of APC was not appropriate as the committee has already decided that "on clinical grounds, the status for certain indications approved by APC should be amber, supported by an ESCA. However, until the commissioning arrangements have been agreed to allow safe transfer of patient care, the status will remain RED".
As the commissioning discussions are on-going, the position remains unchanged.

To date the APC secretary is aware of some of the indications considered for shared care and these include: high risk pregnancy, immobilised patients. A first draft ESCA has been drawn up and includes a list of other indications suggested by the Women's hospital lead.

The commissioners commented that this was a similar situation to Esmya®

where the APC has clarified its position from a pharmaceutical point and the various treatment pathways need to be redesigned. Therefore a business case needs to be prepared by the Trusts' departments that wish to transfer prescribing of enoxaparin to primary care in order for it to be considered and prioritised. It would also be helpful if the same departments across the local Trusts could come together and put a single business case for consideration to ensure a single approach across the health economy.

It was therefore decided that until the commissioning process was resolved there was little value in circulating the draft ESCA as it would need to be reviewed to ensure it was up to date and clinically relevant.

Action: **Trust representatives to go back to their respective departments and relay comments from APC regarding need for business cases.** **Trust leads**

Enstilar®- feedback from HoE FT Dermatologist

Following the APC approval of Enstilar® cutaneous foam at the November meeting and proposal to remove Dovobet® ointment in 6 months' time, feedback was received from one of HoE FT dermatologist. The specialist was concerned that the spray formulation was not appropriate for poorly accessible sites such as the back, whilst it was possible to locate a plaque and apply the ointment. He also questioned the comment that the ointment was poorly tolerated as this was not his professional view. The gel formulation is quite runny and works well on scalp and ears; the ointment is more suitable for trunks and limbs. As there is no cost implication, he requests that all three formulations remain on formulary.

It was suggested that the views of the dermatologists be sought at the end of May 2017 with regards to choice of formulations to remain on formulary.

Action: Contact dermatologists across Trusts at end of May 2017 to seek their views on formulations of calcipotriol 50mcg/g & betamethasone 0.5mg/g to remain on formulary. **APC sec**

1216/12 **Summary of decline to prescribe forms-**

- SWBH summary was circulated for information. A CCG representative requested if any follow-up was required by Primary care, and also requested that these be shared with Heads of Medicines Management.
  It was confirmed that the purpose of these summaries was to identify recurring issues and for these to be raised with appropriate clinicians.
  In the case of RED drugs, the Trust leads should discuss with the clinician requesting GPs to pick up prescribing and remind them of the hospital only status.
  In the case of AMBER and GREEN drugs, a discussion can take place in Primary care.
  BCH Trust will prepare a summary of "decline to prescribe" to present to APC.

Action: Birmingham Children's representative to submit summary of decline to prescribe forms to APC. **BCH Trust lead**

- Propantheline for hyperhidrosis:

At the last APC Away day (September 2016), HoEFT confirmed that there are currently 5-10 patients on propantheline for hyperhidrosis under their care, and

that a recent "decline to prescribe" form had prompted this discussion.
The members present agreed that the omission of propantheline from Chapter 13 was an oversight and not deliberate.

Current formulary options are:

- Aluminium salts GREEN
- Botulinum toxin A RED
- Glycopyrronium RED

In view of the licensed status and the lower acquisition cost compared to glycopyrronium, it was agreed to add propantheline to the APC formulary under section 13.12 for hyperhidrosis.

A discussion followed regarding the RAG status; there are other oral antimuscarinics which are less expensive and potentially more effective than propantheline.

Primary care members confirmed that they would be comfortable using an antimuscarinic off -label e.g. oxybutynin IR after a trial of aluminium salts as they are familiar with this drug and its side effect profile, before referring their patient to secondary care.
It was therefore agreed to add oxybutynin IR and propantheline on the formulary to section 13.12 as follows:

- Oxybutynin Immediate release (IR)- GREEN
- Propantheline: AMBER- specialist recommendation

This decision was ratified by the committee.

Actions:

- **Add Oxybutynin Immediate release (IR) for section 13.12 as GREEN** **APC sec**
- **Add propantheline to section 13.12 as AMBER- specialist recommendation** **APC sec**

1216/13 NICE Technology Appraisal (TAs)

There were 3 NICE Technology Appraisals published in November 2016 (one commissioned by NHSE and two commissioned by CCGs).

- TA418 Dapagliflozin in triple therapy for treating type 2 diabetes: Dapagliflozin in a triple therapy regimen is recommended as an option for treating type 2 diabetes in adults, only in combination with metformin and a sulfonylurea – commissioned by CCGs, providers are NHS hospital trusts, community providers and primary care. GREEN status on formulary.

- TA419 Apremilast for treating moderate to severe plaque psoriasis: Apremilast is recommended as an option for treating chronic plaque psoriasis in adults whose disease has not responded to other systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and ultraviolet-A light), or when these treatments are contraindicated or not tolerated, only if the criteria set out in the TA are met. This guidance replaces NICE TA368. Commissioned by CCGs, although use in paediatrics (from specialised paed dermatology centres) would be NHSE, if commissioned. Providers are NHS hospital trusts. RED status.

Action: Update APC formulary with decisions on NICE TAs. **APC sec**

12**16/14** **Trust Chairs non-Formulary approvals**

- A summary from UHB NHS FT was included in the papers circulated for the meeting. For information.
- The chair reminded the Trust representatives to submit this information on a regular basis as this was useful.

Action: trust leads to submit Trust Chairs non-formulary approvals on regular basis . **Trust leads**

Any other business:

1. **Essential Shared Care Agreements (ESCAs)- age range**
   A CCG received communication which suggested that the child and adolescent mental health service in Solihull was using the oral antipsychotics ESCA. It transpired that it was not the case but it did highlight the fact that the ESCA did not state that this was only for patients over 18 years of age, and could have been misused in a younger population. In fact the majority of the approved ESCAs did not clarify the appropriate age range.
   APC members commented antipsychotics are used in different patient age ranges depending on the licensed indication.
   It was therefore agreed to review the current ESCAs and include a statement regarding the appropriate patient population covered by the shared care agreement.

Action: Review current ESCAs and include a statement regarding the appropriate patient population covered by the shared care agreement. **APC sec**

2. **Essential Shared Care Agreements (ESCAs)- ratification for use**
   The APC chair has received feedback from a team at BSMHFT which highlighted difficulties in getting a group of local GPs to prescribe oral antipsychotics under the current shared care agreement approved by APC. The reason stated was that the practice had not specifically approved the ESCA, nor had it been approved by the Local Medical Committee (LMC). Furthermore, as the document was an editable PDF, they were able to delete the sections they did not want to do, mainly around monitoring.
   It was confirmed that the only editable sections were for patient-specific information to be entered.
   It was confirmed that there is no process for individual practices to approve the ESCA, but they are invited to participate and can decline using the appropriate form.
   With regards to the LMC role, it is not to advise the practices what they can or can't prescribe but how to navigate the shared care process and how to interpret the GMC guideline.
   A blanket "decline to prescribe" needs to be fed back to the Medicines Management leads for the CCG or should be raised at the CCG's Clinical Quality Review Group (CQRG) to address any specific issue.

3. **Pramipexole M/R**
   A Trust representative has enquired if pramipexole M/R was included in the APC formulary. The APC secretary commented that as the ESCA only covers use of immediate release formulation, the M/R preparation was not

included.
It was suggested that an abbreviated application form for the M/R preparation be submitted to the APC for consideration, together with a revised ESCA to support.

Action: UHB Trust clinician to submit an abbreviated application form for pramipexole M/R, together with revised ESCA to support transfer of prescribing. **UHB Trust clinician**

The chair thanked the members for their input today. The meeting closed at 16:45 pm.

Date of next meeting: Thursday 12th January 2017 14:00 – 16:45
Conference Room A,
Birmingham Research Park,
Vincent Drive.
Birmingham B15 2SQ.