**AREA PRESCRIBING COMMITTEE MEETING**
**Birmingham, Sandwell, Solihull and environs**
Minutes of the meeting held on
**Thursday 14th March 2019**
Venue – Birmingham Research Park
Vincent Drive, Birmingham, B15 2SQ

**PRESENT:**

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| Dr Lisa Brownell | BSMHFT (Chair) |
| Dr Paul Dudley | Birmingham and Solihull CCG |
| Prof Mark DasGupta | Birmingham and Solihull CCG |
| Dr Nashat Qamar | Birmingham and Solihull CCG |
| Nilima Rahman-Lais | Birmingham and Solihull CCG |
| Dr John Wilkinson | Birmingham and Solihull CCG |
| Jonathon Boyd | Sandwell & West Birmingham CCG |
| Satnaam Singh Nandra | Sandwell & West Birmingham CCG |
| Dr Sonul Bathla | Sandwell & West Birmingham CCG |
| Dr Angus Mackenzie | Sandwell & West Birmingham NHS Trust |
| Dr Mark Pucci | UHB NHS FT |
| Gurjit Sohal | UHB NHS FT |
| Katy Davies | UHB NHS FT |
| Carol Evans | UHB NHS FT/Birmingham and Solihull CCG |
| Dr Sangeeta Ambegaokar | Forward Thinking Birmingham Partnership |
| Alison Tennant | Birmingham Women's and Children's NHS FT |
| Nigel Barnes | BSMHFT |
| Kalpesh Thakrar | Birmingham Community Healthcare NHS FT |
| Ravinder Kalkat | Midlands & Lancashire CSU |
| Kuldip Soora | Midlands & Lancashire CSU |
| Daya Singh | Midlands & Lancashire CSU |

**IN ATTENDANCE:**
No attendees

| No. | Item | Action |
|---|---|---|

**0319/01 Apologies for absence were received from:**

Liz Thomas, Birmingham and Solihull CCG
Inderjit Singh, UHB NHS FT, deputy attended
Melanie Dowden, Birmingham Community Healthcare NHS FT, deputy attended
Dr Neil Bugg, Birmingham Women's and Children's NHS FT

It was confirmed that the meeting was quorate.

**0319/02 Items of business not on agenda** (to be discussed under AOB)

- Mexiletine
- Lubiprostone
- NaCl 1mmol/ml oral solution licensed product available

**0319/03 Declaration of Interest (DoI)**

The Chair reminded members to submit their annual declarations of interest to the APC Secretariat.

**0319/04 Welcome and Introductions**

The Chair welcomed everyone to the meeting today.

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.

The February meeting was not quorate. The decisions from the meeting were highlighted to members and agreed.

**0319/05 Budesonide 1mg orodispersible tablets (Jorveza®) - New drug application –** Dr Falk Pharma UK Ltd

The application was deferred with a request for additional information on patient numbers and unmet need.

**0319/06 Pan-Birmingham Respiratory Group Asthma Guidelines** – For discussion / ratification

The Chair directed members to the Pan-Birmingham Respiratory Asthma guidelines circulated with the papers for the meeting. Colonel Wilson, Respiratory Medicine Consultant, UHB NHS FT was acknowledged for his input to the guidance.

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

- The guidance includes the recent changes to asthma treatments approved onto the BSSE APC formulary.
- The 1-page summary has been moved to the end of the guidance.
- There has been extensive input from senior asthma clinicians from primary and secondary care.
- The guidance requires approval from individual organisations governance processes.

- Members commended the Pan-Birmingham Respiratory group for the comprehensive guidance produced.

Decision summary: APC approved the guidelines pending authorisation from individual organisation governance processes

**ACTIONS**:

- **Relay APC approval to Pan-Birmingham Respiratory Network pending authorisation from individual organisations** **APC sec**

**0319/07 BSSE APC Away day documents –** For discussion/ratification

The away day was held on Thursday 28th February 2019 covering formulary chapters 6 – Endocrine, 7 Obstetrics, gynecology and urinary tract disorders and chapter 4 Central Nervous System - Pain section only.

The APC secretary directed members to the enclosure Endocrine chapter. The full proposals and rationale from the away day are documented within the enclosures. A summary was relayed to the members:

**Chapter 6 – Endocrine**

- Representatives from the Diabetes Medicines Management Advisory Group (DMMAG) Professor Hanif and Hanadi Ghannam Alkhder attended the away day to propose changes to diabetes agents.
- Fiasp® is proposed as Amber with ESCA following further discussion with DMMAG members. The cohorts are defined as "For use in pregnancy to achieve post prandial blood glucose control. Use in type 1, type 2 or individuals who develop gestational diabetes when other insulins have been unsuccessful."
- Addition of the insulin glargine biosimilar, Semglee® to formulary as Green.
- DMMAG proposed to widen the cohorts for insulin degludec in type 1 and type 2 diabetes patients. APC request new application including evidence for the proposed indications/cohorts.
- Sitagliptin to be kept as Green on formulary. Alogliptin first line. APC suggest promoting more education regarding first line choices using the DMMAG produced Type 2 diabetes algorithm.
- Canagliflozin – amend status from Green to Amber due to adverse effects. See MHRA Drug safety update: *SGLT2 inhibitors: updated advice on increased risk of lower-limb amputation (mainly toes).*
- Proposal to rationalise GLP1 agonists. Lixisenatide and exenatide, exenatide prolonged release changed to non-formulary. To confirm the NICE TAs for these agents have been withdrawn.

Dr Gleeson and Dr Toogood, Consultant endocrinologists, UHB NHS FT attended to present the following proposals

- Specialists requested the addition of the international PCOS guidelines to the formulary entries for metformin and cyproterone.
- The specialists proposed finasteride status Red to Amber for hyperandrogenism. Spironolactone and letrozole to be added. Link to guidelines to all entries.
- Members noted none of the agents are licensed for PCOS and the

guidance highlighted has not been ratified within the UK. Members agreed to request full drug applications due to off-label use.

- Ethinylestradiol 10microgram tablets amend from Red to Amber Specialist recommendation. 2microgram tablets remain Red. For induction of puberty in female patients who cannot tolerate first line treatment.
- A member noted the cost of ethinylestradiol 10microgram tablets being approximately £200 for 21 tablets.
- Bromocriptine change from Red to Amber as no different to prescribing cabergoline or quinagolide.
- Testosterone preparations amend from Amber to Green as per the other routinely used hormone replacement agents. Specialists are receiving decline to prescribes (DtPs) from primary care. Away day action was to check DtPs received from Trusts. UHB NHS FT HGS representative stated there have been a small number or Decline to prescribes for testosterone preparations.
- Request to add modified-release hydrocortisone tablets (Plenadren®) to formulary. APC confirmed new drug application required.
- Cinacalcet for complex primary hyperparathyroidism specialists requested to add as Amber with ESCA. APC confirmed new drug application required.
- Bisphosphonates formulary entries to be updated with MHRA drug safety update on atypical femoral fracture. *The need for continued bisphosphonate treatment should be re-evaluated periodically particularly after 5 or more years of use.*
- Somatostatin analogues – specialists requested a change from Red to Amber for acromegaly at the away day. Members requested further information which has been received and circulated with the papers. It states specialists are satisfied with the homecare arrangements currently in place. Retain Red rating.

**Chapter 7 – Gynaecology, Obstetrics and urinary-tract disorders**

The APC secretary directed members to the Chapter 7 enclosure. The full proposals and rationale from the away day are documented within the enclosures. A summary was relayed to the members:

- UHB NHS FT received comments from Umbrella service quoting the Faculty of Sexual and Reproductive Healthcare guidance which states women should have access to their choice of contraception which is safe and sensible, i.e. all contraceptives should be available.
- UHB NHS FT representative has invited Umbrella specialists to attend a future APC to provide further input and rationalise the chapter.
- Specialists queried why duloxetine is Red status for stress incontinence. At the time of addition to the formulary, the preparation was new and deemed less cost-effective. A generic preparation is now available. Members agreed to change the status to Green.
- Specialists queried if tadalafil is recommended on formulary for lower urinary tract symptoms (LUTS) in benign prostatic hyperplasia (BPS). Members clarified it is non-formulary and a separate entry indicating this should be added to the formulary. Approved on formulary for erectile dysfunction only.

**Chapter 4 Central Nervous System – Pain section only**

- Co-codamol – remove reference to use in chronic pain only as co-codamol is often used as part of post-operative bundles for pain relief. Add note to formulary entry regarding cautions/contraindications as detailed in enclosure.
- Topiramate to be added as Amber specialist recommendation for migraine prophylaxis.
- Lidocaine patches have limited clinical value for all indications besides post-herpatic neuralgia, its licensed indication. Remove need for RICaD. Non-formulary for all other indications. Trusts to communicate this internally.
- Pregabalin and gabapentin entries to be updated with the controlled drug legal and best practice restrictions which come into force April 1st 2019.

**Hormone Replacement Therapy recommendations**

- The recommendations were presented by Satnaam Singh Nandra on behalf of the HRT group. HRT group members Dr Pratima Gupta, Consultant Obstetrics & Gynaecology – UHB NHS FT HGS, Elaine Stephens, Senior Menopause Clinical Nurse Specialist - Birmingham Womens and Childrens NHS Foundation Trust, Miss Lynne Robinson - Consultant Obstetrician and Gynaecologist Lead of Fertility, Menopause & Reproductive Endocrine Services - Birmingham Womens and Childrens NHS Foundation Trust, Louise Whitticase - Lead Pharmacist Women's and Neonatal Services, Birmingham Women's and Children's NHS Foundation Trust and Dr Louise Newson General Practitioner (GP) with Specialist interest
- The HRT group propose removing the Progesterone micronized (Utrogestan®) RICaD and widening the cohort. Satnaam has relayed to the group requirement to make an application to APC.

**Away day ESCAs/RICaDs**

- It was noted a draft Fiasp® ESCA has been produced by DMMAG and the next step is wide circulation with member organisations.
- Members agreed to retain insulin glargine RICaD, degludec RICaD, ibrandonic acid 50mg tablets ESCA, Utrogestan ESCA. The sodium clodronate and denosumab ESCAs are currently being reviewed.
- Members agreed to withdraw the dutasteride (Avodart®) RICaD, Lixisenatide RICaD, Ibrandonic acid 150mg tablets ESCA, Withdraw need for buprenorphine patches ESCA and lidocaine patches RICaD which were initially requested at formulary harmonisation.

**ACTIONS**:

- **Make formulary amendments as discussed.** **APC sec**
- **Circulate Fiasp® ESCA for wide circulation with member organisations** **APC sec**

**0319/08 Flash Glucose Monitoring: National arrangements**

The Chair directed members to the *Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients.*

The original APC position statement was based on Regional Medicines Optimisation Committee (RMOC) recommendations to APCs and stated the use of flash glucose monitoring systems was not commissioned.

The availability of flash glucose monitors has been considered within the NHSE Long Term Plan and a revised NHSE funding statement has been produced. The APC endorse the criteria set out within the NHSE document and it will replace the original BSSE APC statement on the formulary website.

The Chair invited questions or comments from members. Discussion points/concerns raised included:

- A member queried whether initiation and maintenance would occur in secondary care and which sector would be expected to carry out the review at 6 months. A CCG representative explained the arrangements were currently being agreed, however initiation is likely to occur in secondary care. The review could take place as a telephone conversation with the patient.
- The members discussed what was meant by 'improvement in psychosocial wellbeing'.
- A member queried if audit data on the use of Freestyle Libre® is continuing to be collected. A member clarified there is not a national requirement for collecting data, however locally there is a requirement to record HbA1c levels as part of the ongoing reauthorisation process. A neighbouring CCG area have worked with secondary care to evaluate the benefits of flash glucose systems for approximately a year and the data shared.
- The formulary will be updated with CCG arrangements after 1st April 2019.

**ACTION**:

- **Update formulary with NHSE arrangements** **APC sec**

**0319/09** **BSSE APC Dermatology ESCAs** – For ratification

**Azathioprine ESCA**

- A primary care member suggested the ESCA contain a requirement for the specialist to send blood results to the General Practitioner (GP) within 5 days if bloods are taken in secondary care as part of follow up with dermatology. This will prevent the blood test being repeated in primary care which is inappropriate. GPs are declining ESCAs because they are unable to undergo safe monitoring without sight of the pathology results.
- A secondary care member recalled in certain areas GPs are not acting on abnormal blood results flagged up by secondary care that are unrelated to the condition detailed in ESCA.
- A primary care member noted GPs are responsible for the general medical care of the patient therefore should be acting on abnormal blood results relating to the patient's general condition.
- The primary care member clarified they would expect the appropriate specialist for the condition the ESCA relates to, to send the relevant pathology results to the GP to enable the GP to continue prescribing the agent within the ESCA.
- A secondary care representative member stated the clinic letter to the GP should include the blood results as per the usual procedure.
- Secondary care members remarked it is unlikely they can send blood results to GPs within a 5 days turnaround.
- A primary care member added within their practice they must review

pathology results on the day they arrive and queried how long secondary care would take to review pathology results. A member clarified the laboratory will ring and alert secondary care clinicians of any blood results that are vastly abnormal, other results are reviewed routinely.

- A member highlighted that the concerns raised are not specific to medicines which require an ESCA.
- Members agreed the ESCA can be approved.
- Members agreed an electronic system to share blood results is needed and there should be a separate piece of work highlighting this to enable safer prescribing.

**Ciclosporin ESCA**

- A member queried the "After commencing treatment" section of the ESCA which states *Regular monitoring of blood pressure (BP) is required during ciclosporin therapy*. How often do they want BP checked if normal with ciclosporin.
- Members agreed the frequency of BP monitoring is a clinical decision dependent on the individual patients clinical circumstances.

**Methotrexate ESCA**

- A member queried the stipulation within the ESCA which states "ensure the methotrexate patient information leaflet and dosage record booklet is presented to the consultant" and questioned whether primary care are able to enforce this.
- The member asked if injectable methotrexate requires different monitoring arrangements or has different associated risks to oral methotrexate. The member highlighted the requirement for *PIIINP monitoring after 3 months.* A member clarified this is a recommendation from the British Association of Dermatology (BAD).
- It was not clear in the ESCA if it is primary care or secondary care who monitor PIIINP. PIIINP is not within the GP responsibilities section however in the pre-treatment assessment section states "to monitor PIIINP at least every 3 months."

Decision summary: Dermatology azathioprine and ciclosporin ESCAs are approved. Revise methotrexate ESCA.

**ACTION**

- **Clarify monitoring requirements and responsibilities for Methotrexate ESCA, particularly PIIINP** **APC sec**
- **Publish Dermatology Azathioprine and Ciclosporin ESCAs** **APC sec**

**0319/10** **Regional Medicines Optimisation Committee recommendations –** For discussion

The Chair directed members to the RMOC Position Statement: Maintaining Patency of Central Venous Catheter.

No comments were made.

**0319/11** **Minutes of the meeting held on Thursday 14th February 2019 –** for ratification

The minutes of the meeting held on Thursday 10th January 2019 were discussed for accuracy.

- Page 4; Reword action to "Amend guidance and seek approval by individual organisations governance processes"
- Page 5; Reword to "UHB NHS FT request more time due to the complexity of switching from tinzaparin to Inhixa®"

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

**0319/12 Matters Arising**

The Chair moved onto the action table for comments and updates:
(See separate document attachment for updated version). Consider actions closed if not discussed.

The outstanding actions include:

- 0219/06 BSSE APC Type 2 Diabetes prescribing guidance **Update:** Amend guidance and seek approval by individual organisations governance processes
- 0219/07 BSSE APC Primary Care Clinical Pathway for AF Detection and Management Amend the document as discussed **Update:** In progress
- 0219/09 BSSE APC RICaDs for review Circulate ivabradine and ranolazine RICaDs for specialist review. **Update:** comment received from UHB NHS FT Cardiologist stating ivabradine RICaD is no longer needed. APC decided to retain RICaD following comments from primary care; APC sec to relay to consultant and thank for the feedback. Close action
- 0119/07 BSSE APC Valproate medicines ESCA Amend ESCA and bring to future meeting – **Update:** Scheduled for April
- 1118/08 BSSE APC Dermatology ESCAs **Update:** Close action
- 1119/AOB Identified issues with shared care documents – **Update:** Comments received from specialists. Amendments in progress. Scheduled for April meeting.
- 0418/08 APC membership list – for ratification. **Update:** In progress.

**0319/13 NICE Technological Appraisals (TAs)**

In February 2019, there were 5 TAs published; of these, 3 is NHSE commissioned and 2 are not recommended.

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

**Any other business:**

**1. Mexilitene**

Mexiletine is an antiarrhythmic agent, indicated for the treatment of ventricular arrhythmia. It is available from 'special order' manufacturers or specialist importing companies in the form of 150mg, 200mg and 250mg capsules. 100 mg of mexiletine hydrochloride is equivalent to 83.31 mg of mexiletine base. The current BSSE APC formulary status for mexiletine as treatment for

ventricular arrhythmia is amber, to be used with local trust approval.

A licensed preparation of mexiletine became available in March 2019. Namuscla® 167 mg hard capsules is indicated for treating myotonia in adult patients with non-dystrophic myotonic disorders. Each capsule contains mexiletine hydrochloride corresponding to 166.62 mg mexiletine. An SPC is available but the product is not listed in the BNF and Drug Tariff.

Unlicensed mexiletine prescriptions now require an accompanying letter from the prescriber stating their intention to prescribe an unlicensed over a licensed preparation, and the rationale for this. The new arrangement has led to a prescriber, having been informed of availability of a licensed version, issuing Namuscla® off label for treating ventricular arrhythmia. The patient was previously prescribed mexiletine 200mg BD at the request of a specialist from the local Trust.
The price, supplied by the pharmacy, was £5000 for one month's supply of Namuscla,® and previously £350 for unlicensed mexiletine 200mg capsules.

**ACTION: Add non-formulary entry for mexiletine 167mg hard capsules (Namuscla®) to APC formulary** **APC sec**

**2. Sodium chloride 1mmol/ml oral solution**

Sodium chloride 1mmol/ml oral solution is currently Red on formulary. There is now a generic licensed preparation available. UHB NHS FT – HGS are aware of use small numbers in neonates with cystic fibrosis, where all other items are prescribed in primary care and carers are having to attend Trust to obtain supplies.

A member raised from a safety perspective, there are many sodium chloride preparations selectable on GP systems and there is the potential for incorrect product being selected.

A member clarified use is in small number of patients for short period of time.

**ACTION: Amend formulary entry to Amber specialist recommendation** **APC sec**

**3. Lubiprostone**

The manufacturer has discontinued lubiprostone (Amitiza®). NICE TA guidance has therefore been withdrawn. Amend to non-formulary.

**ACTION: Amend formulary entry to non-formulary with annotation** **APC sec**

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

**Date of next meeting: Thursday 11th April 2019 14:00 – 16:45**
**Birmingham Research Park.**