AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 11th April 2019
Venue – Birmingham Research Park
Vincent Drive, Birmingham, B15 2SQ

PRESENT:

Dr Paul Dudley	Birmingham and Solihull CCG (Chair)
Prof Mark DasGupta	Birmingham and Solihull CCG
Liz Thomas	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
Prof Jamie Coleman	UHB NHS FT
Inderjit Singh	UHB NHS FT
Katy Davies	UHB NHS FT
Carol Evans	UHB NHS FT/Birmingham and Solihull CCG
Dr Sangeeta Ambegaokar	Forward Thinking Birmingham Partnership
Dr Neil Bugg	Birmingham Women's and Children's NHS FT
Nigel Barnes	BSMHFT
Ravinder Kalkat	Midlands & Lancashire CSU
Kuldip Soora	Midlands & Lancashire CSU
Daya Singh	Midlands & Lancashire CSU

IN ATTENDANCE:

Dr Joanna Whitehouse for item 0419/05	UHB NHS FT

No.	Item	Action

0419/01 Apologies for absence were received from:

Dr Dhiraj Tripathi, UHB NHS FT
Dr Angus Mackenzie, Sandwell & West Birmingham Hospitals NHS FT
Dr Sonul Bathla, Sandwell and West Birmingham CCG

It was confirmed that the meeting was quorate.

0419/02 Items of business not on agenda (to be discussed under AOB)

- Mexiletine
- Shared care arrangements
- Strontium ranelate
- Insulin lispro biosimilar
- Formulary wording for medicines used in paediatrics

0419/03 Declaration of Interest (DoI)

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

0419/04 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.

0419/05 Paravit-CF® - New drug application – ParaPharm Development Ltd

It was established that there were no Declarations of Interests for ParaPharm Development Ltd.

The Chair welcomed Dr Joanna Whitehouse, Respiratory consultant and Cystic Fibrosis (CF) lead, UHB NHS FT, to the meeting and invited her to present the application for Paravit-CF®.

Dr Whitehouse explained that over ninety percent of CF patients are pancreatic insufficient, so require fat soluble vitamins from birth. Currently, they are having to take a concoction of tablets. Dr Whitehouse stated the average vitamin D level in East Birmingham for the general population is 19nmol/L.

Dr Whitehouse explained patients commence fat soluble vitamins A, D, E and K at a young age. As adults their risk of osteoporosis goes up to 25% risk and are often found to have low vitamin D levels and required to take further supplementation, increasing the number of tablets they require.

Dr Whitehouse explained vitamin K is not routinely prescribed for CF patients in childhood. It is usually required by adulthood for both osteoporosis and haemoptysis.

Dr Whitehouse stated Paravit-CF® is more cost effective and reduces the tablet burden, replacing separate vitamin supplements for those patients who prefer a combined supplement.

Dr Whitehouse explained that the average compliance with medication is still under 50% for CF patients and acknowledged this was the same for any chronic disease. The compliance drops to approximately 30% with addition of nebulisers.

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

- A member referred to the cost comparison section of the application. Vitamin A and D capsules, colecalciferol, menadiol and alpha tocopherol are stated as the alternative regime. The member asked whether all the 350 estimated number of patients to be treated are on this regime currently. Dr Whitehouse responded all patients should be prescribed vitamin K, however the dose of vitamin K used can vary according to patients INR. Haemoptysis patients require 10mg vitamin K. Dr Whitehouse estimated 40% of patients are on vitamin K, nearly all patients are prescribed vitamin D and all patients are prescribed vitamin E (alpha tocopherol).
- Members sought clarification regarding the number of estimated patients to be treated across the BSSE APC geographical patch. Dr Whitehouse confirmed the estimated patient number from the clinic would cover the wider region beyond the BSSE APC patch.
- A member stated that CF patients are likely to be on a large number of medicines and reducing the tablet burden by even a small amount can make a positive difference to them.

The Chair thanked Dr Whitehouse for attending the meeting, for answering all the questions from the APC members and advised her that the decision would be relayed within 5 working days, in line with APC policy.

Further discussion points in the absence of the specialist included:

- A member agreed with the suggestion patient adherence is likely to improve if required to take two Paravit-CF® capsules compared to separate supplements.
- A member queried the cost comparison section of the application, stating if all patients to be treated are on the stated regime there is benefit to the health economy.
- A member commented as the intended cohort is defined, prescribing is not likely to be widespread. In addition, initiation would occur by specialist or on specialist recommendation reducing the likelihood of creep in prescribing.

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

Patient Safety: No issues identified

Clinical effectiveness: Correcting a known deficiency

Strength of evidence: Alternative way of delivering established treatment

Patient Factors: Reduced pill burden, potential for improved adherence

Cost-effectiveness or resource impact: Cost effective compared to current described regime

Place of therapy relative to available treatments: First tier

National guidance and priorities: N/A

Local health priorities: CCGs supportive

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: None

Decision Summary: Approved onto APC formulary as Amber - initiation or recommendation for GP initiation by specialist in CF.

ACTION:

- **Relay decision to Dr Whitehouse by Thursday 18th April 2019** **APC sec**
- **Add Paravit-CF® to the APC formulary as Amber** **APC sec**

0419/06 Wound care product recommendation - Benehold TASA®

The Chair directed members to the application for Benehold TASA® wound product evaluation.

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

- It was confirmed Benehold TASA® is proposed to replace Tegaderm® hydrocolloid on the formulary.

Decision Summary: Approved onto APC formulary with RAG status of Green. Tegaderm® hydrocolloid to be changed to non-formulary status.

ACTIONS:

- **Relay decision to the Wound Care Group by Thursday 18th April 2019** **APC sec**
- **Add Benehold TASA® to the APC formulary as Green and change Tegaderm® hydrocolloid to non-formulary** **APC sec**

0419/07 BSSE APC Valproate medicines ESCA – For ratification

The Chair directed members to the enclosure for the BSSE APC Valproate medicines effective shared care arrangement (ESCA) and amended risk assessment form for review.

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

- A member raised the national Medicines and Healthcare products Regulatory Agency (MHRA) annual risk acknowledgment form was recently revised and published online.
- A member commented that the updated risk acknowledgment form is more pragmatic and takes into consideration women who may be exceptional in the view of the clinician.
- Members agreed to adopt the national risk assessment form by way of adding reference to it within the ESCA. This prevents having to update the ESCA each time the risk acknowledgement form is updated.

ACTION:

- **Amend valproate ESCA with reference to updated MHRA risk acknowledgment form and publish** **APC sec**

0419/08 BSSE APC Degarelix ESCA – For ratification

The Chair directed members to the ESCA updated by Richard Gledhill, Prostate Cancer Nurse Specialist and Urology MDT lead, UHB NHS FT. The ESCA was circulated for consideration by member organisations with no further comments received.

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

- A CCG representative noted GPs had raised concerns regarding use in primary care due to the amount of time taken for the product to disperse appropriately when reconstituted therefore time spent by nurses on administration. In addition, some parts of the original ESCA were unclear.
- A member stated the ESCA should be more explicit to state degarelix is administered by trained practice staff and not by patients.

ACTION:

- **Amend degarelix ESCA as discussed and publish** **APC sec**

0419/10 Regional Medicines Optimisation Committee recommendations – For information

The Chair directed members to the RMOC Newsletter – 2019 Issue 2

0419/11 Minutes of the meeting held on Thursday 14th March 2019 – for ratification

The minutes of the meeting held on Thursday 14th March 2019 were discussed for accuracy.

- Page 3; Amend spelling to hyperandrogenism
- Page 5; Amend spelling to ibandronic acid

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

0419/12 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:

- 0319/07 BSSE APC Away day documents Circulate Fiasp® ESCA for wide consultation with member organisations. **Update:** Comments received. Scheduled for May meeting

- 0319/08 Flash Glucose Monitoring: National arrangements Update formulary with NHSE arrangements. **Update:** RAG status amended to

Amber. Birmingham and Solihull CCG flash glucose monitoring policy to be hyperlinked within the formulary entry. Close action.

- 0319/09 BSSE APC Dermatology ESCAs Clarify monitoring requirements and responsibilities for Methotrexate ESCA, particularly PIIINP **Update:** Awaiting dermatology specialists feedback

- 0219/06 BSSE APC Type 2 Diabetes prescribing guidance Amend guidance and seek approval by individual organisations governance processes **Update:** In progress with DMMAG

- 0219/07 BSSE APC Primary Care Clinical Pathway for AF Detection and Management Amend the document as discussed **Update:** In progress.

- 1119/AOB Identified issues with shared care documents – **Update:** Apomorphine, sodium clodronate and denosumab scheduled for future meeting.

- 0918/12 RMOC recommendations Highlight differences between BSSE APC Position Statement on Use of Manufacturers' Free of Charge Medicines Schemes and the RMOC advice on Free of Charge Medicines and feedback to APC. **Update:** On hold as RMOC are amending this guidance. Close action.

- 0418/08 APC membership list – for ratification. **Update:** In progress.

- 0716/11 Enoxaparin commissioners position statement. Draft ESCA for enoxaparin for consultation. **Update:** Draft ESCA discussed at Feb 19 meeting. On hold. Provider trusts to engage with Birmingham and Solihull CCG to resolve commissioning decisions. Action updated to read 0419/AOB.

0419/13 NICE Technological Appraisals (TAs)

In March 2019, there were 8 TAs published; of these, 5 is NHSE commissioned, 1 CCG commissioned and 2 are not recommended.

The CCG commissioned NICE TA:

Ertugliflozin as monotherapy or with metformin for treating type 2 diabetes [TA572]

Green status agreed as per other agents in this group.

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

Any other business:

1. Mexiletine

A CCG representative raised the issue of mexiletine prescribing discussed at the March APC meeting which highlighted a licensed preparation of mexiletine which became available in January 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 base.

Prior to this there was not a licensed mexiletine preparation available and therefore have been 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.

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 price, supplied by the pharmacy, was £5000 for one month's supply of Namuscla,® and previously £350 for unlicensed mexiletine 200mg capsules.

It is not possible for CCGs to make arrangements in primary care that would preclude the dispensing of the licensed product for any prescription for mexiletine 200mg capsules nor prevent specials prices rising towards the licensed prices. APC to consider re-designation of mexiletine from amber to red with supplies moving to hospital.

There were 200 prescriptions which were dispensed and cost Birmingham and Solihull CCG £60,000. The cost will rise considerably to approximately three quarters of a million pounds with no additional benefit.

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

- A member questioned the benefit of changing the RAG rating to Red. Mexiletine use for arrythmias is well known.
- The CCG representative reiterated the supply chain cannot be controlled. The community pharmacist who fulfills the prescription is entitled to use their professional judgement and dispense the branded product for which they would be reimbursed.
- A member asked whether the prescribing support software can encourage the prescribing of the unlicensed product. Members agreed this would not prevent the dispensing of the branded product by community pharmacies.
- A member suggested potential repatriation of patients to hospital for review by cardiology specialists for alternative or ongoing supply.
- A Sandwell and West Birmingham CCG representative discussed a small number of patient's supply across SWB CCG was to be issued by the Trust due to inconsistency of supply within primary care. For many of these patients mexiletine was a last line option.
- There is concern if a GP receives a letter warning them of the unlicensed status of mexiletine 200mg capsules then they will be unlikely to prescribe it.
- Members agreed a discussion was necessary regarding a commissioning pathway to ensure the repatriation is properly funded.
- A member explained a neighboring CCG is taking the approach of retaining mexiletine prescribing in secondary care for a defined

indication. Cardiologists presented a compelling case for mexiletine use and place in therapy. The view from community pharmacists was they would be inclined to dispense the licensed product in primary care.

ACTION:

- **Further discussion required between CCGs and Trusts regarding potential arrangements for mexiletine supply** — **BSOL CCG/UHB NHS FT**

2. Shared care arrangements

A GP practice has highlighted that when initiating a shared care agreement a member Trust is sending a letter to the patient's practice stating they accept the terms of the ESCA. However, if the GP would like a signed copy of the ESCA they should log in to a certain area of the Trust/CCG website, download the ESCA, sign it and send it to the Trust specialist to sign.

A CCG representative explained that the new process has come from the Trust Quality Improvement forum with the aim of moving the ESCA process online. It is unclear whether there was any engagement with local GPs however, the majority have not raised concerns. Engagement with pharmacy was not sought. An IT/electronic solution to shared care agreements to move the process online was felt needed hence the new arrangement.

A member was concerned that ESCAs could more easily be overlooked using this electronic arrangement and paper copies demonstrate the shared care agreement has been considered fully. Asking practices to locate the ESCA online may increase risk of omission.

Members felt the ESCA should be sent to GPs alongside the clinical letter in whichever format the clinical letter is sent to the GP, whether electronic or as paper copy to prevent omissions.

The Trust have acknowledged the initial lack of engagement and has invited interested parties to the Trust Quality Improvement forum to discuss the process.

Members felt the APC need to consider a strategic approach to how shared care arrangements are managed on the interface in a more efficient way. Moving away from a manual approach may encourage effective shared care.

3. Strontium ranelate

Strontium ranelate is available on the market after being discontinued by manufacturer in August 2017. NICE TA 161 which referred to strontium was also modified due to its discontinuation. On discontinuation, the APC decided to change the RAG status to non-formulary.

Members considered how the product should be reinstated on the formulary.

It was clarified the product is licensed. Members agreed the cost of strontium should be considered before reinstating onto the formulary. Members agreed to ask applicants to complete an abbreviated application for APC consideration.

4. Insulin lispro Sanofi

There is a new insulin biosimilar insulin lispro Sanofi (equivalent to Humalog). A Trust are seeking clarification on the process for APC approval.

It was recognised Insulin Semglee® was added on to the formulary following submission of the RMOC insulin safety checklist therefore the RMOC checklist should be submitted for APC consideration.

5. Formulary wording for medicines used in paediatrics

A proposal from the away day asks members to consider adding some phrasing to the formulary to support primary care prescribing when a specialist recommends a Green or Amber formulary medication for a licensed indication but for a child that is younger than the age at which the license begins.

For example, ranitidine used in children younger than 3 years old. UHB NHS FT HGS report receiving decline to prescribes for this and other medicines commonly used off-label in paediatrics yet are known use, have an established evidence base and recommended in the British National Formulary for Children.

The phrasing proposed:

The APC notes that many formulary medications are not licensed for use in the paediatric population.

The APC advises GPs to consider specialist prescribing recommendations for Green and Amber medicines that are not subject to ESCAs or RICaDs in combination with the information provided in the BNFC which goes beyond that of marketing authorisations. The BNFC has been designed for rapid reference and the information presented has been carefully selected to aid decisions on prescribing.

Members agreed the wording should be rephrased to avoid labelling the medicines as 'unlicensed' as this is inaccurate.

It was agreed that the wording would be revised and reconsidered at a future APC meeting.

ACTION: Wording to be revised and reconsidered by APC **APC sec**

The Chair thanked the members for their input today. The meeting closed at 15:30.

Date of next meeting: Thursday 9th May 2019 14:00 – 16:45
Birmingham Research Park.