AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the meeting held on
Thursday 13th February 2020
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
Nilima Rahman-Lais	Birmingham and Solihull CCG
Liz Thomas	Birmingham and Solihull CCG
Dr Nashat Qamar	Birmingham and Solihull CCG
Dr Angus Mackenzie	Sandwell and West Birmingham NHST
Satnaam Singh Nandra	Sandwell and West Birmingham CCG
Dr Sonul Bathla	Sandwell and West Birmingham CCG
Dr Neil Bugg	Birmingham Women's and Children's NHS FT
Nigel Barnes	BSMHFT
Dr Sangeeta Ambegaokar	Forward Thinking Birmingham Partnership
Gurjit Sohal	UHB NHS FT
Carol Evans	UHB NHS FT/Birmingham and Solihull CCG
Prof Inderjit Singh	UHB NHS FT
Dr Mark Pucci	UHB NHS FT
Kuldip Soora	Midlands and Lancashire CSU
Ravinder Kalkat	Midlands and Lancashire CSU

IN ATTENDANCE:

Mr Mohammad Tallouzi for item 0220/05	Birmingham and Midland Eye Centre
Mr Abdul-Jabbar Ghauri for item 0220/06	Birmingham and Midland Eye Centre
Gurjinder Samra	Midlands and Lancashire CSU (Observer)

No.	Item	Action

0220/01 Apologies for absence were received from:

Dr John Wilkinson, Birmingham and Solihull CCG
Melanie Dowden, Birmingham Community Healthcare NHS FT
Prof Jamie Coleman, UHB NHS FT
Dr Dhiraj Tripathi, UHB NHS FT
Lisa Brownell, BSMHFT
Maureen Milligan, The ROH NHS FT

It was confirmed that the meeting was quorate.

0220/02 Items of business not on agenda (to be discussed under AOB)

- Sodium oxybate
- Resin for hyperkalaemia
- Formulary status of Seroflo®
- Ertugliflozin
- Items which should not routinely be prescribed in primary care

0220/03 Declaration of Interest (DoI)

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

0120/04 Welcome and Introductions

The Chair welcomed everyone to the meeting today.

The Chair reminded members, 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.

0220/05 Latanoprost/Timolol preservative free eye drops (Fixapost®) - new drug application

The Chair welcomed Mr Mohammad Tallouzi, surgical practitioner in ophthalmology, Birmingham and Midland Eye Centre (BMEC) to the meeting and invited him to present the application for latanoprost/timolol preservative free eye drops (Fixapost®).

Fixapost® is a preservative-free formulation combining a prostaglandin (latanoprost) and a beta blocker (timolol). Open angle glaucoma and ocular hypertension are common conditions. First line treatment is a prostaglandin and second line are a prostaglandin combined with a beta blocker. Ocular surface disease is an issue in patients with glaucoma. The prevalence of ocular surface disease increases with age. Currently available preservative free formulations combining a prostaglandin and beta-blocker are Ganfort® single dose containers (bimatoprost and timolol), Taptiqom® single dose containers (tafluprost and timolol) and Fixapost®. Cosopt® contains a different class of agent, dorzolamide combined with timolol. The clinical efficacy has been found to be similar between all the products mentioned.

Fixapost® is the most cost-effective preservative free option available. Mr Tallouzi added the preservative free formulations are restricted to those cases where they are necessary such as in severe ocular surface disease, epithelial

toxicity or allergies to preservatives. In addition, preservative free formulations are used to improve surgical outcomes for upcoming surgical procedures.

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

- It was clarified Fixapost® is the most cost-effective preservative free formulation of a prostaglandin and beta blocker combination.
- A member suggested Fixapost® replace Ganfort® on the formulary. Mr Tallouzi confirmed there are no trials showing Ganfort® is superior to Fixapost® therefore considers this a reasonable suggestion. Mr Tallouzi's only concern is Ganfort® contains a different prostaglandin and may cause lapse in control of the condition when switching patients to Fixapost®. A member clarified patients previously established on non-formulary drugs normally continue with their treatment.
- Mr Tallouzi confirmed ophthalmology clinicians across the region have supported the formulary application for addition of Fixapost® but not necessarily for substituting Ganfort® for Fixapost® on formulary.
- A member asked if there are any clinically significant differences between Ganfort® and Fixapost®. Mr Tallouzi confirmed there are not. Ganfort® has been prescribed more as it was the only option available.
- A member raised the application states Fixapost® would replace Xalacom®. Mr Tallouzi stated Xalacom® contains a preservative. Fixapost® would replace Xalacom® within the ocular surface disease cohort of patients.
- A member asked what proportion of the glaucoma cohort would require preservative free preparation. Mr Tallouzi answered patients aged over 60 or 65 are more at risk of developing ocular surface disease. Another cohort are those who are undergoing a surgery. For reference, at BMEC 25 boxes of Monoprost® were issued last month. Mr Tallouzi reiterated the preservative free formulations are not indicated for all glaucoma patients. Mr Tallouzi stated there are guidelines in place at BMEC which recommend preservative free formulations for a limited number of indications.

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

Further discussion points in the absence of the representatives included:

- Members agreed a preservative free option for a prostaglandin/beta blocker is required and Fixapost® is the most cost-effective product available.
- Ganfort® will become non-formulary but should be continued for existing patients.

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

Patient Safety: Equivalent

Clinical effectiveness: Equivalent

Strength of evidence: Strong

Patient factors: Prevalence of ocular surface disease increases with age

Cost effectiveness or resource impact: Cost effective compared to alternatives

Place of therapy relevant to available treatments: 3rd line

National guidance and priorities: SMC approved in patients who have proven sensitivity to preservatives

Local health priorities: CCGs supportive

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: None required

Prescribing data: preservative-free preparations are monitored by CCGs

Decision Summary: Amber Specialist Recommendation

ACTIONS:

- **Add Fixapost® to formulary as Amber Specialist Recommendation** **APC sec**
- **Amend Ganfort® to non-formulary.** **APC sec**
- **Relay decision to Mr Tallouzi by Thursday 20th February 2020** **APC sec**

0220/06 Ciclosporin 1ml/ml eye drops (Verkazia®) – new drug application

The Chair welcomed Mr Abdul-Jabbar Ghuari, consultant in paediatric ophthalmology, Birmingham and Midland Eye Centre to the meeting and invited him to present the application for ciclosporin 1ml/ml eye drops (Verkazia®).

Verkazia® is the only product licensed for the treatment of moderate to severe vernal keratoconjunctivitis (VKC). The condition is potentially sight threatening and symptoms are disabling. There is no other licensed alternative. Ciclosporin is available in other formulations, for example Restasis® licensed for dry eye and Optimmune®, a veterinary preparation. The alternative preparations are not licensed for this indication and there are availability issues within primary care. Protopic® ointment (tacrolimus) is also sometimes used off-label for this indication.

The efficacy of Verkazia® for this cohort has a proven success rate of 54% as reported in the Vekta study. In clinical practice, Mr Abdul-Jabbar Ghuari has found the drug is effective. Treatment avoids multiple flare ups which would be treated with corticosteroid eye drops, avoiding the potential associated side effects such as glaucoma and cataracts. In addition, avoiding sight threatening complications which are common.

Mr Abdul-Jabbar stated the eye drops are continued for 18 months to 3 years as most patients grow out of VKC by adolescence. They are not always used four times daily as it is not practical or sustainable when treating young patients.

Topical ciclosporin has been used for a long time and safety is proven. Systemic side effects are rare. Approximately 20% of patients experience

either transient itchiness and redness. In practice, Mr Abdul-Jabbar has only had to discontinue treatment with Verkazia® for two patients and commence Protopic®.

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

- A member asked if there are other ciclosporin 0.1% topical eye preparations available. Mr Abdul-Jabbar stated ciclosporin 0.1% is available on formulary as Ikervis®, a licensed treatment for severe dry eye in adults. The manufacturer's have branded the same agent as Verkazia® for use in children.
- Mr Abdul-Jabbar is currently using Ikervis® off-label to treat VKC.
- Mr Abdul-Jabbar clarified he does not expect Verkazia® to be initiated in primary care; specialist initiation is necessary.
- A member queried if Verkazia® is likely to be prescribed for children under 4 years old. Mr Abdul-Jabbar does not see VKC in that age range.

The Chair thanked Mr Abdul-Jabbar for attending the meeting, for answering all the questions from the APC members and advised him that the decision would be relayed within 5 working days, in line with APC policy.

Further discussion points in the absence of the representatives included:

- Members confirmed Verkazia® is cost-neutral to Ikervis®.
- A member confirmed there is small use within their Trust for the appropriate indication and cohort. These patients are being followed up regularly within Trust according to disease state and duration of treatment.

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

Patient Safety: Similar off-label alternatives

Clinical effectiveness: Equivalent to alternatives

Strength of evidence: Randomised control trial

Patient factors: N/A

Cost effectiveness or resource impact: Verkazia® only licensed treatment for VKC. Cost neutral to off-label alternative.

Place of therapy relevant to available treatments: First line

National guidance and priorities: recommended for use by SMC and AWMSG

Local health priorities: CCGs supportive

Equity of access: N/A

Stakeholder views: N/A

Implementation requirements: None

Prescribing data: N/A

Decision summary: Amber Specialist Initiation

ACTIONS:

- **Add Verkazia® to formulary as Amber Specialist Initiation** **APC sec**
- **Relay decision to Mr Abdul-Jabbar by Thursday 20th February 2020** **APC sec**

0220/07 Dacepton® new drug application – additional information

The Chair directed members to the further information submitted by the applicant to support the new drug application for Dacepton® considered in December 2019.

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

- Members agreed the Dacepton® pen device and cartridges are cost-effective. The pen device will be supplied by manufacturer.
- Members noted the number of reservoirs required by the patient is determined by the dose of apomorphine infusion.

Decision Summary: The APC approve the Dacepton® pen device and cartridges. Clarity is required around the number of patients requiring reservoir and how many reservoirs would be required per patient based on an average dose.

ACTION:

- **Add Dacepton® solution for injection in cartridge to APC formulary as Amber Specialist Recommendation** **APC sec**
- **Relay decision to Dr Wright by 20th February 2020** **APC sec/UHB NHS FT**

0220/08 BSSE APC ESCAs/RICaDs – for ratification

The Chair directed members to the denosumab ESCA.

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

- A primary care representative raised concerns with the monitoring requirements for denosumab within primary care.
- It was clarified denosumab prescribing occurs within a few GP practices across the area and this should be supported. GPs are invited to participate in shared care but under no obligation to do so.
- Uptake of denosumab prescribing within primary care is small.
- A primary care representative described barriers/reluctance to prescribing by GPs; there is no formal training on the medication and device. In addition, the requirement for the GP to arrange a DXA scan at 3-5 years is challenging. There was a question as to whether secondary care can arrange the DXA scan after 3-5 years.
- GPs are required to check the bone passport which may lead to extra appointments; should this occur in primary care.
- The term ‘regularly’ should be clarified under specialist responsibilities.
- It was clarified the denosumab injection occurs every 6 months.
- Members queried if it was possible for secondary care clinicians to recall patients after 3-5 years for the DXA scan or if they would face

similar issues as primary care.

ACTION:

- **Clarify arrangements for DXA scan with denosumab treatment** **APC sec**

The Chair directed members to the lithium and oral antipsychotic ESCAs.

- The Lithium ESCA was reviewed at the Central Nervous System away day. Calcium level monitoring was added to ESCA recently following additional comment from BSMHFT.
- The oral antipsychotics ESCA received a response from a Forward Thinking Birmingham (FTB) clinician querying if an age restriction can be added to the oral antipsychotics ESCA.
- A member queried what provision there was for housebound patients to obtain an ECG within primary care. Members agreed this would be a discussion between specialist and GP and may require a clinical decision choosing an alternative antipsychotic agent.
- A member queried what is the place in therapy for anticholinergic drugs for movement disorder. Procyclidine is the most commonly used but not all patients require an anticholinergic.
- Pimozide is non-formulary and not used so needs to be removed from the ESCA.

The Chair directed members to the rifaximin RICaD.

- There were no further comments on the rifaximin RICaD and it is approved.

ACTION:

- **Publish the lithium and oral antispsychotics ESCAs subject to amendments discussed above.** **APC sec**
- **Publish rifaximin RICaD on formulary website** **APC sec**

0220/09 Ethical and religious implications of animal derived substances in medicines

The Chair directed members to the draft statement on 'Ethical and religious implications of animal derived substances.' UHB NHS FT identified a need for a statement on the APC website after a concern was raised that vegan options were not supported on the formulary website.

The statement was approved.

ACTION:

- **Publish statement on formulary website** **APC sec**

0220/10 Summaries for Decline to Prescribe and DTC Chairs Non-formulary approvals

The Chair directed members to information provided by Sandwell and West Birmingham NHST and Birmingham Community Healthcare Trust.

0220/11 Declines by Trust DTC

None were reported

0220/12 RMOC recommendations

The Chair directed members to the 'Updated RMOC advice for adoption as local policy: Free of Charge (FOC) Medicines Schemes.'

- A member raised point 7.9 within the policy which states "the application must meet commissioners' prior notification requirements." There was comment this could cause a significant delay and would depend on the urgency of the FOC.
- The BSSE position statement on FOC schemes reflects the RMOC advice.

The Chair directed members to the 'Standard principles for Medicines prior approval forms.'

- The templates for use within Birmingham and Solihull CCG are currently being reviewed.

The Chair directed members to the 'RMOC advisory statement Sequential use of biologic medicines.'

- A member raised the NHS Constitution which tells us if a clinician and patient consider it appropriate therapy, they have a right to access NICE approved treatments.
- Birmingham and Solihull CCG do not have a policy currently.

0220/13 Minutes of the meeting held on Thursday 9th January 2020 – for ratification

The minutes of the meeting held on Thursday 9th January 2020 were discussed for accuracy.

- Page 9 under Primary Care Network Directed Enhanced Service (DES) 1st sentence; amend to 'there is an emphasis to reduce the carbon footprint of the NHS'; 2nd sentence; amend to '… there is a plan to encourage the use of dry powder inhalers.'

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

0220/ 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:

- 1219/07 BSSE APC RICaDs for aliskiren and amiodarone – Amend amiodarone RICaD as discussed.

- 1119/07 - BSSE APC Anti-dementia treatments ESCA - Inform APC of changes to the commissioning of anti-dementia medicines.

- 0919/05 - Chapter 11 Eye - Formulary chapter review - Trust to complete drug application form alongside ophthalmology specialists. UHB aware Close action.

- 0919/AOB - Matters arising - Dental products on formulary - Schedule away day for the review of dental products. Approach BCHC.

- 0719/06 - BSSE Away day documents - Trusts to develop report on LMWH prescribing.

- 0619/AOB - Azathioprine for haemolytic anaemia - Produce Azathioprine ESCA for haemolytic anaemia.

ACTION: Follow up Palliative care formulary update with specialist palliative care subgroup **APC sec**

0120/15 NICE Technological Appraisals (TAs)

In January 2020, there were 5 TAs published; of these, 2 are NHSE commissioned, 1 is CCG commissioned and 2 are not recommended.

The CCG commissioned NICE TA is:

- NICE TA 617: Lusutrombopag for treating thrombocytopenia in people with chronic liver disease needing a planned invasive procedure.

Red status agreed.

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

Any other business:

1. Sodium oxybate

There was a discussion surrounding the appropriate route for formulary inclusion. An application requires cost information and there may be a requirement to submit a business case to CCGs if cost exceeds the financial limit that can be authorised by the CCG representatives.

2. Formulary status of Sereflo®

Sereflo® is cost effective compared to Seretide® and should be on formulary. There is a review programme occurring within Birmingham and Solihull CCG.

ACTION: Add Sereflo® to formulary as GREEN **APC sec**

3. Ertugliflozin

Diabetes Medicines Management Advisory Group (DMMAG) have raised there is evidence of lower limb amputation risk within the ertugliflozin SPC. Amber status agreed as per DMMAG recommendation.

ACTION: Amend formulary status of ertugliflozin to Amber Specialist Recommendation. **APC sec**

4. Items which should not routinely be prescribed in primary care

A Sandwell & West Birmingham CCG pharmacist queried the RAG status of aliskiren in relation to the NHSE guidance. Members agreed to retain Amber status as small use within a member trust for existing patients and use overseen by the speciality.

The pharmacist also queried why some bath and shower emollients remain Green on formulary. A member noted the BATHE study has been extensively discussed at previous APC meetings when it was first published and reviewed by the dermatology teams. The section was ratified at the Skin chapter away day with dermatology specialist input and Green status for these items was considered appropriate. The policy is referred to within the formulary entries.

It was stated recommendations to the APC should go through the organisation's APC representative.

5. Resins for hyperkalaemia

A trust representative noted the TAs have been published for 2 agents and requires clarity from CCG whether agents are CCG commissioned. CCG and Trust representatives to liaise outside of APC.

The Chair thanked the members for their input today. The meeting closed at 16:10.

Date of next meeting: Thursday 12th March 2020 14:00 – 16:45
Birmingham Research Park.