AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs
Minutes of the virtual meeting held on
Thursday 13th August 2020
Venue – Microsoft Teams

PRESENT:

Dr Lisa Brownell	BSMHFT (Chair)
Dr Paul Dudley	Birmingham and Solihull CCG
Prof Mark Dasgupta	Birmingham and Solihull CCG
Liz Thomas	Birmingham and Solihull CCG
Dr John Wilkinson	Birmingham and Solihull CCG
Dr Nashat Qamar	Birmingham and Solihull CCG
Jonathan Boyd	Sandwell and West Birmingham CCG
Dr Sonul Bathla	Sandwell and West Birmingham CCG
Emily Horwill	Sandwell and West Birmingham NHST
Dr Angus Mackenzie	Sandwell and West Birmingham NHST
Alison Tennant	Birmingham Women's and Children's NHS FT
Melanie Dowden	Birmingham Community Healthcare NHS FT
Nigel Barnes	BSMHFT
Gurjit Sohal	UHB NHS FT
Carol Evans	UHB NHS FT/Birmingham and Solihull CCG
Jeff Aston	UHB NHS FT
Prof Jamie Coleman	UHB NHS FT
Dr Mark Pucci	UHB NHS FT
Jonathan Horgan	Midlands and Lancashire CSU
Kuldip Soora	Midlands and Lancashire CSU
Daya Singh	Midlands and Lancashire CSU

IN ATTENDANCE:

Dr Niraj Mistry for item 0820/05	UHB NHS FT
Dr Gordon Mazibrada for item 0720/05	UHB NHS FT

No.	Item	Action

0820/01 Apologies for absence were received from:

Prof Inderjit Singh, UHB NHSFT (deputy attended)
Dr Dhiraj Tripathi, UHB NHS FT (deputy attended)
Nilima Rahman-Lais, Birmingham and Solihull CCG
Maureen Milligan, The ROH

It was confirmed that the meeting was quorate.

0820/02 Items of business not on agenda (to be discussed under AOB)

- Dementia medicines ESCA
- Lanthanum (Fosrenol®) tablets
- Chair nominations

0820/03 Declaration of Interest (DoI)

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

0820/04 Welcome and Introductions

The Chair welcomed everyone to the meeting.

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.

0820/05 Delta-9-tetrahydrocannabinol and cannabidiol (Sativex®) oromucosal spray new drug application

The Chair welcomed Dr Niraj Mistry and Dr Gordon Mazibrada, consultant neurologists, UHB NHS FT to the meeting. Introductions were carried out for the benefit of the attendees.

The Chair invited Dr Mistry to present the application for delta-9-tetrahydrocannabinol and cannabidiol (Sativex®) oromucosal spray.

Dr Mistry began by highlighting Sativex® is another option for multiple sclerosis (MS) patients who fail to respond adequately to other conventional pharmacological therapies such as baclofen or tizanidine. Dr Mistry highlighted that there is a lot of media attention in cannabinoid and cannabis related products. He added Sativex® is not a panacea i.e. it doesn't work for everyone nor is it a disease-modifying agent but is reserved for patients who fail to respond to conventional medicines and are proven responders to Sativex® as per the manufacturer's pay-for-responders scheme.

Dr Mazibrada added he treats around 4 or 5 patients within his clinic who self-fund for Sativex® treatment. Sativex® would be recommended for patients who fail to respond to other anti-spasticity therapies. In his experience, most patients manage their symptoms with around 4-6 sprays per day. This is compared to the licensed dosage which can go up to 12 sprays per day. The pay-for-responders scheme provides Sativex® free of charge for a trial period. Specialists assess that there is at least 20% reduction in spasticity-related symptoms on a modified Ashworth scale.

The applicants for this formulary application anticipate that some cost savings to the healthcare economy would occur from reduced hospital admissions and reduced usage of other anti-spasticity drugs.

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

- A member queried how spasticity is measured objectively and noted pain and spasticity can coincide, therefore Sativex® may be inappropriately prescribed for pain. Dr Mazibrada agreed that pain is related to spasticity. A visual analogue scale is used to measure spasticity. Sativex® may be used for painful spasms for example when a patient wakes up in the night due to spasms despite the patient having been treated with another agent that evening. Suitability would depend on feedback from the individual patient and other factors to determine if a patient is responding to their current treatment. Dr Mistry added patients assessed to have neuropathic pain with the absence of spasticity would not be considered suitable for Sativex®.
- A member queried the duration of treatment with Sativex®. Dr Mazibrada noted patients are assessed on a 6 to 12-month basis within the MS clinic. Patients' also have telephone access to MS nurses. Dr Mistry added a proportion of patients will discontinue use as Sativex® is not a panacea. It may help a small proportion of patients for a period of time.
- A member queried if a 'Red' formulary status could be considered for Sativex® eligible patients are having very close contact with the MS specialists and this relates to only a small number of patients. Dr Mistry responded that he would not like to differentiate Sativex® from other anti-spasticity agents as he sees it as an alternative to the other conventional medicines. Once baseline monitoring is established to be within range, there is no further mandatory monitoring and therefore Dr Mistry does not anticipate a large burden on primary care.
- A member asked if there was a potential for 'creep' i.e. prescribing outside of the licensed indication for example for pain. The applicants reiterated there is no role for Sativex® in neuropathic pain. A Trust representative added Sativex® would not be recommended for other than the licensed indication and prescribing would be monitored.
- A member asked if there are likely to be issues surrounding holding stock in community pharmacies due to potential risks of diversion. A member confirmed Sativex® is listed in the Drug Tariff and is a licensed product therefore should be available within community pharmacies. Members agreed the issue around diversion was not specific to Sativex®.
- A member queried how clinicians will assess patients who are using cannabis they obtained themselves i.e. illegally and how would clinicians monitor these patients who may end up using cannabis concurrently with Sativex®. Dr Mazibrada raised there are known hospital admissions due to the psychiatric effects of illegal cannabis. Availability of Sativex® decreases chance of patients using unregulated products. Dr Mistry has reports from patients who have tried unregulated cannabis and have not found it useful and those patients who have derived benefit would prefer to use a licensed version.
- A member raised, as stated within the application, the cohort of patients is estimated at 70 for the first year and queried how many patients

would be suitable candidates per year on an ongoing basis. The applicants agreed the initial cohort will be larger than the ongoing need. Dr Mistry estimated between 20-30 patients per year following the initial year. He explained that there is strong demand from a small and selective cohort. Specialists will be clear on the licensed indication and the specific circumstances where patients are eligible. The MS speciality audit their practice.

The Chair thanked Dr Mistry and Dr Mazibrada for attending the meeting, and for answering all the questions from the APC members and advised them 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:

- A member commended the applicants for a balanced and objective application.
- A member raised as small patient numbers are affected, Sativex® would be suitable as Red. Further views were raised that if the patient numbers were high then a business case is required.
- A CCG representative confirmed Sativex® will require additional investment beyond delegated limits and the recommendation has been passed to the relevant commissioning forum for prioritisation.
- The CCG representative highlighted NICE guidance has changed from not recommended, to a recommended trial and treatment approach and has investigated the evidence to support this change. The member quoted two sections from NICE: “the committee considered the evidence from two economic evaluations but noted they had contradictory conclusions about the cost effectiveness of the spray so they considered results from a new economic model that they had specifically developed for the cannabis guideline” “the model estimates that the spray would offer sufficient QALY gains if a reduction in spasticity led to a halving of management costs and the acquisition cost of the spray was also reduced in addition to the pay-for-responders scheme”. The CCG representative went on to estimate a cost per QALY considering the QALY versus the acquisition cost and not other factors, of between £112k-£168k which was a higher amount than NICE would ordinarily approve. In addition, there has been no reduction in cost of medication and the reduction in management costs is yet to be proven.
- A CCG representative confirmed the application has been through the initial prioritisation process in BSOL CCG for funding but would require a business case as the next stage.
- A member asked if the evidence for effectiveness for sufficient. Views were this is established.

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

Patient Safety: Potential for abuse/diversion mitigated by controlled drug status and decision pathway developed by MS specialists

Clinical effectiveness: Established licensed product. Evidence of effectiveness for a defined cohort

Strength of evidence: Moderately effective as per NICE recommendation

Patient factors: n/a

Cost effectiveness or resource impact: Evidence in NICE CG falls outside normal cost per QALY that NICE would consider. Resource impact estimation for 70 patients as per application would be up to a million pounds.

Place of therapy relevant to available treatments: 3rd line before invasive treatments. Where other pharmacological treatments are ineffective

National guidance and priorities: NICE CG. Not within cost per QALY envelope NICE usually considers

Local health priorities: Low position on CCG CPAG list

Equity of access: Currently underway with CCG

Stakeholder views: MS Society welcome NICE guidance however disappointed with lack of commitment to funding Sativex®

Implementation requirements: n/a

Prescribing data: n/a

Decision Summary: APC wish to support the addition of Sativex® on formulary but are aware of the resource impact. Decision deferred until commissioning arrangements are agreed.

Rationale: Sativex® is a clinically effective treatment with moderate evidence with the potential to be very effective in a small cohort of patients where other pharmacological treatments are ineffective. There are concerns with cost-effectiveness particularly given the methodology used to assess cost-effectiveness within the NICE guidance and the assumptions made that have not materialised. The resource impact would approximately be a third of a million in the initial year and up to one million should it go up to 200 patients as stated in the original application, over several years. The resource impact is beyond the CCG delegated limits and requires prioritisation at the relevant commissioning forum.

ACTIONS: **APC sec**

- **Relay decision to applicants by Thursday 20th August 2020** **APC sec/BSOL CCG/APC Chairs**
- **Write a letter to applicants clarifying the current commissioning position**

0820/06 BSSE APC ESCA denosumab

The Chair directed members to the denosumab ESCA

- The ESCA should reflect the NICE TA 204 for prevention of osteoporotic fractures in postmenopausal women.
- A member raised primary care colleagues have not supported shared care for this agent. As per all shared care arrangements GPs are invited to participate but are under no obligation to do so.
- APC will continue to monitor 'decline to prescribes' to assess if further support is required for primary care colleagues

ACTIONS:

- **Amend ESCA to reflect NICE TA 204 as discussed** — **UHBNHS FT/CSU**

0820/07 BSSE APC Management/development subgroup Terms of Reference

The Chair directed members to the terms of reference for the APC Management/development subgroup. No further comments were made.

0820/08 Declines by Trust DTC

None were reported

0820/09 RMOC recommendations

There were no RMOC recommendations released in July 2020.

0820/10 Minutes of the meeting held on Thursday 9th July 2020 – for ratification

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

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

0820/11 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:

- 0720/06 Apomorphine solution for infusion (Dacepton) cost comparison Confirm place in therapy for Apo-Go Update: applicant confirmed having both Apo-Go® and Dacepton® on formulary would help deliver patient choice

- 0720/AOB Acetylcisteine on formulary. Consult with respiratory specialists and bring comments to a future APC meeting. Update: A UHB representative confirmed a number of patients who transfer from Birmingham Children's hospital require the sachets and effervescent tablets which are also a licensed preparation. **ACTION: Annotate formulary entry to include effervescent tablets**

- 1219/07 BSSE APC RICaDs aliskiren and amiodarone. Amend amiodarone RICaD as discussed. In progress

- 1119/07 - BSSE APC Anti-dementia treatments ESCA. Inform APC of changes to the commissioning of anti-dementia medicines. Update: Birmingham and Solihull CCG and the BSMHFT are in a position to support the Amber status of anti-dementia agents from 1st September 2020. The associated ESCA will be discussed under AOB. The CCG and Trust have agreed generic prescribing in most cases except for

galantamine MR capsules and rivastigmine patches where the most cost-effective options are recommended – these will be highlighted on the formulary.

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

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

0820/12 NICE Technological Appraisals (TAs)

In July 2020, there were 2 TAs published; both are NHSE commissioned.

Red status agreed

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

Any other business:

1. **Anti-dementia medicines ESCA**

In line with the changes to the commissioning arrangements, the anti-dementia ESCA has been finalised by Birmingham and Solihull CCG and BSMHFT. The following areas have been updated. Under 'Specialist responsibilities' addition of point 10 b – "confirmation of any failure to attend to be followed up GP responsibilities" and point 2 any significant deterioration in physical or mental health should be informed back to the Trust, point 4 the check for patient's pulse to be completed at annual review or sooner if symptoms. A statement regarding If lack of compliance suspected refer to specialist. The medication profile list includes a referral to the formulary for formulary options

ACTIONS:

- **Amend formulary to reflect change in commissioning arrangements for anti-dementia medicines on 1st September 2020** **APC sec**
- **Upload amended anti-dementia medicines ESCA to formulary on 1st September 2020** **APC sec**

2. **Lanthanum (Fosrenol®) tablets**

A CCG representative highlighted a prescription request from a Trust to a neighbouring CCG to prescribe lanthanum (Fosrenol®). The request was denied as the patient is under the dialysis unit and therefore the request falls with NHSE and should not be GP prescribed. The formulary should be amended to reflect the commissioning arrangements. A UHB representative highlighted there may be exceptional circumstances where a more patient centred approach is required.

ACTION: Amend formulary entry to clarify commissioning arrangements in dialysis **UHB NHSFT/APC sec**

3. **Chair nominations**

The term of office for the Joint Chairs is two years and therefore it is due for APC review. Chair nominations will be requested via email. This can be a nomination from beyond current committee members. Instructions will be provided on the email.

The Chair thanked the members for their input today. The meeting closed at 15:45.

Date of next meeting: Thursday 10th September 2020 via Microsoft Teams