AREA PRESCRIBING COMMITTEE MEETING
Birmingham, Sandwell, Solihull and environs

Minutes of the meeting held on
Thursday 10th December 2020
Venue – Microsoft Teams

PRESENT:

Dr Lisa Brownell	BSMHFT (Chair)
Dr Paul Dudley	Birmingham and Solihull CCG
Nilima Rahman-Lais	Birmingham and Solihull CCG
Dr Nashat Qamar	Birmingham and Solihull CCG
Dr John Wilkinson	Birmingham and Solihull CCG
Dr Sonul Bathla	Sandwell and West Birmingham CCG
Satnaam Singh Nandra	Sandwell and West Birmingham CCG
Dr Angus Mackenzie	Sandwell and West Birmingham NHST
Emily Horwill	Sandwell and West Birmingham NHST
Dr Sangeeta Ambegaokar	Birmingham Women's and Children's NHS FT
Alison Tennant	Birmingham Women's and Children's NHS FT
Melanie Dowden	Birmingham Community Healthcare NHS FT
Nigel Barnes	BSMHFT
Carol Evans	UHB NHS FT/ Birmingham and Solihull CCG
Prof Jamie Coleman	UHB NHS FT
Dr Mark Pucci	UHB NHS FT
Gurjit Sohal	UHB NHS FT
Prof Inderjit Singh	UHB NHS FT
Dr Jeff Aston	UHB NHS FT
Jonathan Horgan	Midlands and Lancashire CSU
Graham Reader	Midlands and Lancashire CSU
Daya Singh	Midlands and Lancashire CSU

IN ATTENDANCE:

Prof Kristien Boelaert for item 1220/05	UHB NHS FT
Prof Wasim Hanif for item 1220/06	UHB NHS FT
Dr Amar Puttanna for item 1220/06	Sandwell and West Birmingham NHST
Dr Srikanth Bellary for item 1220/06	Sandwell and West Birmingham NHST
Dr Manjusha Rathi for item 1220/06	Sandwell and West Birmingham NHST
Hanadi Alkhder for item 1220/06	Birmingham and Solihull CCG
Gurpreet Kaur for item 1220/06	Sandwell and West Birmingham CCG
Dr Will Lester for item 1220/13	UHB NHS FT
Dr Charalampos Kartsios for item 1220/13	UHB NHS FT

No.	Item	Action

1220/01 Apologies for absence were received from:

Prof Mark Dasgupta, Birmingham and Solihull CCG
Liz Thomas, Birmingham and Solihull CCG
Dr Dhiraj Tripathi, UHB NHS FT
Jonathan Boyd, Sandwell and West Birmingham CCG
Kuldip Soora, Midlands and Lancashire CSU

It was confirmed that the meeting was quorate.

1220/02 Items of business not on agenda

See under AOB below.

1220/03 Declaration of Interest (DoI)

- Dr Nashat Qamar - part of an educational workshop which was sponsored by Novo Nordisk.
- Dr Manju Rathi - has given one GP educational event which was sponsored by Sanofi.
- Dr Bellary - Attended a diabetes conference in 2020 which was funded by Sanofi.
- Dr Puttanna - has been involved in an educational discussion group meeting with Novo Nordisk
- Prof Hanif - was a principal investigator for the Credence study which contributed to the change in canagliflozin license.

1220/04 Welcome and Introductions

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.

1220/05 Liothyronine - new drug application

Professor Kristien Boelaert, Professor of Endocrinology and Honorary Consultant Endocrinologist, UHB NHS FT presented the new drug application for liothyronine. Approximately 10% of patients with hypothyroidism who are established on levothyroxine monotherapy still feel unwell. Liothyronine is perceived to be an important treatment for this small proportion of patients. There is limited clinical and cost effectiveness data for combination of liothyronine & levothyroxine. However, NICE guidance suggests that in certain cases the combination could be considered. The application proposes liothyronine is to be started in secondary care by an endocrinologist before transfer to primary care via an ESCA, once it is confirmed the patient is benefiting from treatment.

<u>Discussion points raised included:</u>

- The following amendments were agreed for the ESCA:
  - Remove reference to the treatment of resistant depression, as outlined in the contraindication section. The ESCA should make it clear liothyronine is to be used for hypothyroidism only.
  - Refer to RMOC guidance on prescribing liothyronine in the indication section of the ESCA.

- Amend specialist responsibilities section to reflect that there will be a 6 month period before prescribing of liothyronine is transferred to primary care.
- Ensure title of ESCA is clear that it is for the combination use of liothyronine and levothyroxine, and also that there is a place in therapy for the combination use in line with RMOC guidance.

- There was discussion on whether use of liothyronine will increase if added to the formulary, as it was recognised primary care clinicians may be encouraged by patients who may be self-funding to be referred to an endocrinologist. Professor Boelaert explained that there are rigorous protocols in place to ensure patients are assessed appropriately and only those who meet the clinical criteria are prescribed liothyronine.

The committee completed the Decision Support Tool for liothyronine as follows:

Patient Safety: No issues

Clinical effectiveness: Benefit in selected patient cohort

Strength of evidence: Weak, but treatment process ensures that liothyronine is discontinued for those patients that do not benefit

Patient factors: Small, selected cohort will benefit

Cost effectiveness or resource impact: Much more expensive than levothyroxine

Place of therapy relevant to available treatments: Specialist initiation and demonstration of benefit required

National guidance and priorities: In line with RMOC, NHS Clinical Commissioners: *Items which should not routinely be prescribed in primary care: Guidance for CCGs Version 2, June 2019***,** and ESCA

Local health priorities: Some pressure from individuals outside of adequate assessment process

Equity of access: Some patients are already self-funding, so some socio-economic effect

Stakeholder views: Some self-funding patients already, some socio-economic effect

Implementation requirements: ESCA

Prescribing data: Yes

Decision Summary: Amber Shared Care with ESCA

Rationale: n/a

ACTIONS: **APC Sec / UHB NHS FT**

- **Add liothyronine tablets to formulary as Amber Shared Care**
- **Relay decision to Professor Boelaert by Thursday 17th December 2020**
- **Amend and publish ESCA subject to above amendments**

1220/06 DMMAG documents

Diabetes Medicines Management Group (DMMAG) members attended the meeting for this item.

The SPC for canagliflozin has been updated to extend the license to include the initiation in those with eGFR <60ml/min in the presence of albuminuria and continuation in those with eGFR <30ml/min, following findings from the Credence study. Dr Bellary explained SGLT2 inhibitors have shown to be beneficial in patients with kidney disease and will complement the use of ACEi and ARBs in this specific patient cohort. It was noted that canagliflozin was given an Amber Specialist Recommendation status due to previous concerns regarding the increased risk of lower limb amputations. It was proposed canagliflozin be given a green status in line with the other SGLT2 inhibitors on the formulary, as evidence from the Credence study has shown that the risk of lower limb amputation is minimal.

Semaglutide is the first oral GLP-1 available for treatment of adults with Type 2 diabetes. Dr Puttanna explained that it is a cost effective option as it saves administration costs. It could replace liraglutide once daily injections which will add further cost improvement.

Toujeo® 300units/ml currently has Amber with Specialist Initiation status, supported by a RICaD for patients with Type 1 or Type 2 diabetes who have nocturnal hypoglycaemia and are on 80 or more units of basal analogue insulin. Dr Rathi explained that the purpose of the application is to remove the RICaD requirement and amend the current formulary entry wording from nocturnal hypoglycaemia episodes to 'problematic hypoglycaemia' with specialist recommendation.

The Primary Care Sick Day Guidance for the Management of Adult Patients with Diabetes Mellitus was introduced to the committee. This has been developed post-COVID.

Discussion points raised included:

- It was recognised that the suggested cohort of patients for Toujeo® 300units/ml use has expanded. It was clarified that Toujeo® 300units/ml will be at the last option in the new insulin pathway for Type 2 diabetes. The Committee agreed to accept the wider indications proposed for Toujeo® 300units/ml but felt it was necessary to retain the RICaD as it is important for shared decision making and to support primary care in its appropriate use. The committee also agreed that it would review the need for the RICaD again in 6-12 months.
- Clarity was sought on the patent expiry date for liraglutide as the drug application suggested it was due to expire in 2021. It was confirmed that the patent expiry date is 2023.

The committee completed the Decision Support Tool for **Canagliflozin** as follows:

Patient Safety: Reassuring regarding previous concerns (over lower limb amputation risk)

Clinical effectiveness: Established

Strength of evidence: Strong (RCT)

Patient factors: Wider patient group access

Cost effectiveness or resource impact: Neutral, prevention of Renal Replacement Therapy (RRT)

Place of therapy relevant to available treatments: Green as per other drug class members – formulary wording remains same

National guidance and priorities: n/a

Local health priorities: Priority patient group

Equity of access: No issues

Stakeholder views: n/a

Implementation requirements: No

Prescribing data: No

Decision Summary: Green, safety issue now resolved

Rationale: n/a

The committee completed the Decision Support Tool for oral **Semaglutide** as follows:

Patient Safety: No issues

Clinical effectiveness: Equivalent to other GLP-1 in class

Strength of evidence: Good

Patient factors: Oral route, not injectable

Cost effectiveness or resource impact: Equivalent to weekly GLP-1. Reduction in education and carer support required

Place of therapy relevant to available treatments: As per GLP-1 class

National guidance and priorities: Benefit compared to injection in Covid-19 situation. Reduced plastic use.

Local health priorities: Benefit vs injection in COVID scenario

Equity of access: Improved access to therapy

Stakeholder views: Patient groups are likely supportive

Implementation requirements: No

Prescribing data: Yes

Decision Summary: Green as per injectable formulation

Rationale: n/a

ACTIONS: **APC Sec**

- **Amend canagliflozin formulary status to Green**
- **Add oral semaglutide to formulary as Green**
- **Amend formulary entry for Toujeo® 300units/ml in line with that agreed above**
- **Upload Primary Care Sick Day Guidance for the Management of Adult Patients with Diabetes Mellitus to APC formulary**
- **Relay decision to DMMAG by Thursday 17th December 2020**

1220/07 BSSE APC RICaD for review – for ratification

The BSSE APC Entresto® RICaD was deferred to January 2021 APC meeting.

1220/08 Updated BAAG guidance – for ratification

The antimicrobial guidelines produced by BAAG have been updated to reflect the NICE rapid guideline for pneumonia. This was approved.

ACTIONS:

- **Publish updated BAAG guidance to APC formulary.** **APC Sec**

1220/09 Co-Chairs applications – for ratification

The APC secretariat explained that two applications had been received. One application had been received from primary care and one from secondary care, therefore no election process was required. The applicants are the current co-chairs of the BSSE APC. The Committee members ratified the appointment of Dr Lisa Brownell and Dr Paul Dudley as co-chairs of the Committee for a period of 2 years until December 2022.

1220/10 Declines by Trust DTC
None were reported

1220/11 RMOC recommendations
There were no RMOC recommendations released in November 2020.

1220/12 Minutes of the meeting held on Thursday 12th November 2020 – for ratification

The minutes were approved and can be uploaded to the APC website and the recording deleted.

1220/13 Low Molecular Weight Heparin (LMWH) – for discussion

Dr Will Lester and Dr Charalampos Kartsios from UHB NHS FT attended the meeting for this item.

The APC secretariat stated the purpose of the options paper was to progress the resolution of the issues regarding LMWH by re-confirming the Committee's previous support of the prescribing of LMWH in primary care within an ESCA and by deciding whether the Committee wished the draft ESCA to be finalised, and to clarify the ongoing commissioning process between Trusts and CCGs.

Discussion points raised included:

- It was recognised that other APCs nationally have agreed shared care agreements or similar arrangements allowing LMWH prescribing in primary care.
- It was stated that prior to the agreement of the current LMWH formulary entry several years ago designating it red, LMWH could be prescribed in primary care. There was no related transfer of funding to Trusts at that time.
- The APC's role is to agree the RAG designation and agree an ESCA.
- The business case from Trusts has not yet been produced.
- There was a discussion on the relative merits of waiting for the business case to be produced and agreed between Trusts and Commissioners before the APC agreed an ESCA, or producing the ESCA now in order to support the business case.
- Examples of potential patient harm, where not prescribing LMWH in primary care in acute situations were described, mainly in the context of pregnancy, for example women with a previous history of DVT in pregnancy who become pregnant. It is not just about patients being initiated on LMWH under an ESCA, but is also about patients receiving appropriate LMWH treatment when there is an initial encounter in primary care. There needs to be provision for such patients to have LMWH prescribed for them immediately in primary care, in cases of acute need.
- The main areas where prescribing in primary care is felt necessary are in pregnancy, patients who cannot have oral anticoagulants and cancer patients. Prescribing LMWH prophylaxis in the context of a hospital admissions and subsequent discharge for medical and surgical patients would remain the responsibility of the Trusts. Acute DVT is not such an issue as there are now community pathways to manage this.
- There is an increasing role for DOACs, meaning that a smaller number of patients will require prolonged LMWH in future.
- Primary care clinicians agreed that in certain circumstances, it is clinically appropriate for LMWH to be prescribed in a primary care setting. An ESCA would be helpful in situations where shared care was appropriate. However, this could only be implemented once commissioning arrangements are in place.
- The draft ESCA was discussed and it was agreed this represented the right direction to take. There was support for initiation in primary care in acute situations. There was a suggestion that a statement by the APC supporting these points would be helpful.
- It was agreed to add the following additional wording to the formulary entry for LMWH 'this should not prevent individuals in primary care providing initial prescriptions in urgent situations e.g. pregnancy where there is a high thrombotic risk', as the APC supports this use prior to any implementation of the ESCA.
- APC members agreed to proceed with of option 2 of the draft ESCA
- It was agreed to list the conditions where the APC supported the use of LMWH under option 2 of the ESCA once the business case had been agreed and the ESCA approved in the APC formulary - deep vein thrombosis, pulmonary embolism, intolerance/unsuitable for oral anticoagulants, certain cancer patients, injectable drug users, paediatric

use - treatment of thrombotic episodes, paediatric use - prophylaxis of thrombotic episodes and pregnant women.

- It was noted Trusts and CCGs will continue to work on the commissioning impact. **APC Sec**

ACTIONS:

- **Update formulary LMWH entries with agreed wording as stated above**
- **Circulate LMWH ESCA for consultation**

1220/14 Matters Arising

The action table was reviewed for comments and updates:
(See separate document attachment for an updated version). Consider actions closed if not discussed.

The outstanding actions include:

- 1120/07 - Hydroxycarbamide ESCA for myeloproliferative disorders – for discussion - APC secretary to establish generic license for hydroxycarbamide Medac ESCA. Trust to liaise with specialist to confirm ESCA. In progress.

- 1020/05 – Colesevelam (Cholestagel®) and Colestipol (Colestid®) new drug application – Amend RiCaDs in line with comments mentioned in meeting. In progress.

- 1020/08 – Trust DtPs and DTC non-formulary approvals – Circulate UHB NHSFT template for Decline to Prescribe non-formulary approvals. In progress.

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

1220/15 NICE Technological Appraisals (TAs)

In November 2020, there were 7 TAs published; 5 are NHSE commissioned, 1 is CCG commissioned and 1 was a terminated TA.

The CCG commissioned NICE TA is:

- Galcanezumab for preventing migraine [TA659}

Red status agreed

ACTION: Update formulary with NICE TAs.

Any other business:

Sodium Oxybate and Pitolisant

A Trust representative raised whether a new drug application is required for sodium oxybate and pitolisant for an existing sleep service. It was noted that sodium oxybate had previously been considered at APC and was given a black RAG rating.

An advisory statement on sodium oxybate was published by RMOC in 2019 to facilitate commissioning decisions relating to sodium oxybate for all adult

patients, (not just patients transitioning to adult services after treatment under NHS England paediatric policy).

It was suggested that commissioning arrangements for the use of sodium oxybate and pitolisant would need to be considered as this would be outside of APCs remit. A drug application would be required for pitolisant; however, a similar commissioning decision would need to be made as with sodium oxybate.

PCN representation at BSSE APC
A CCG representative raised that the local Primary Care Network (PCN) wished to have pharmacist representation at the APC.

APC members felt that the current balance between primary and secondary care representation is satisfactory. There was discussion on how the CCG communicates and represents the views of the PCN, and how this can be represented at the APC.

Legacy prescribing of medicines subject to ESCA
There have been suggestions from prescribers that patients prescribed a drug e.g. antipsychotics, covered by an ESCA prior to the ESCA existence should routinely be referred to secondary care so that prescribing can take subsequently place under the ESCA.

The impact on secondary care that may result should these patients be referred back was discussed. Patients may be stable and not require specialist input if all routine monitoring is being undertaken in primary care. It was recognised that GP practices have been encouraged to review patients on antipsychotics to ensure that there is a consistent approach to managing the cohort of patients. However, the APC agreed that the ESCA is not intended to be applied retrospectively to such patients and referrals back to specialists should be based on clinical need.

It was agreed it was necessary to add additional wording to reflect the APC's position to the APC Terms of Reference and ESCAs.

ACTIONS:

- **Wording for ToR and ESCA to be agreed in Jan 2021 APC meeting**

The meeting closed at 17:30.
Date of next meeting: Thursday 14th January 2020 via Microsoft Teams