South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
15 December 2022 (Meeting held via MS Teams)
Final Minutes

1. Welcome, introductions and apologies

The Chair welcomed attendees to the meeting. Apologies and observers were noted.

2. Conflict of interests – declarations and DOI refresh

The Chair asked that any conflicts of interest with the meeting agenda be declared and that any outstanding declarations be returned. No conflicts were raised.

3. Detailed action notes of the last meeting, minutes and action log:

The action notes and minutes were accepted and approved as an accurate record pending corrections to minor typographical errors. Members were provided with an update on progress against actions due for this month, these were noted, and items closed were agreed.

- **Urgent AoB item tabled for Committee discussion and approval: Interim SEL Clinical antibiotic prescribing Guidance for Group A Streptococcus (GAS) Infection in paediatrics**

The lead authors presented this urgent AoB item, which has been developed through collaboration by all three SEL acute Trusts in response to the significant increase in Streptococcus A cases. Gaps have been identified in the national guidance available via the UK Health Security Agency (UKSHA) for the management of Group A Streptococcus (GAS) infection in children. The gaps relate to the duration of antibiotic therapy and second line treatment options. Feedback has been provided to national and local antimicrobial teams regarding the gaps in the national guidance, in the interim this SEL guidance attempts to address these gaps based on local expert opinion, until the national guidance is updated.

Members provided feedback, including regarding dosing recommendations, formatting and grammatical changes to the guideline.

Committee members approved the SEL interim clinical guidance for GAS infection by consensus pending amendments requested. Committee members agreed as this is an interim guidance and the national guidance is being updated, a short review date of 3 months would be appropriate.

ACTION: SEL Interim Clinical Guidance for Group A Streptococcus (GAS) Infection to be updated in line with discussions and uploaded to the SEL IMOC webpage and circulated for SEL wide dissemination.

Post meeting note: *The interim SEL guidance has since been withdrawn as the national guidance was updated shortly after the December IMOC meeting to include clarity on antibiotic options and treatment duration.*

4. Formulary inclusion of paliperidone (Byannli™) long acting injection for schizophrenia (Amber 3)

The applicant was in attendance and presented this item. An additional long-acting injection (LAI) formulation of paliperidone (Byannli™) has recently become available which enables 6 monthly administration. The existing LAI formulations on the formulary are monthly and 3 monthly preparations.

Benefits of paliperidone LAI include reduction in relapse, reduced hospital admissions, reduced number of days spent in hospital and lower mortality. The 6 monthly LAI paliperidone formulation reduces the need for patients to receive 12 or 4 injections per year and supports to reduce a common barrier to LAI use in primary care, which is often capacity.

A comment was raised regarding the benefit of providing guidance for primary care on the monitoring of prolactin and which antipsychotics require regular prolactin monitoring such as paliperidone. The presenter confirmed this could be developed as well as screening questions for hyperprolactinemia. Members also requested development of guidance to support those GPs who would be happy to switch

patients to the paliperidone 6 monthly preparation as opposed to referring all patients back to the initiating mental health Trust.

Committee members approved the formulary inclusion of paliperidone (Byannli™) 6-monthly LAI for schizophrenia as Amber 3 (shared care) by consensus pending update to the existing shared care guideline for paliperidone LAI, update to the existing formulary recommendation and development of guidance to support GPs in switching patients to Byannli™ in primary care.

ACTION: Shared care prescribing guideline for paliperidone long acting injection to be updated to include Byannli™ and presented at a future IMOC meeting
ACTION: Formulary recommendation 024 to be updated to include Byannli™ and presented at a future IMOC meeting
ACTION: Guidance to support GPs switch patients to Byannli™ in primary care to be developed and presented at a future IMOC meeting

5. Clinical Effectiveness South East London (CESEL) Chronic Kidney Disease (CKD) guide – medicines section

The CESEL leads were in attendance to present this Guide, which has been developed to improve the outcomes of patients with chronic kidney disease (CKD) and reduce the variation in the management of CKD across SEL boroughs. The Medicines section of the guide has been co-produced and led by the Southwark borough Medicines Optimisation Team. The Guide also supports implementation of the NICE Technology Appraisal (TA) for dapagliflozin in CKD.

The proposed management of CKD in primary care was presented as per the draft CESEL CKD guide, which included kidney health checks, patient advice and the pharmacological management of CKD. The London Kidney Network 3 key actions in 3 months has not been incorporated into the guide as local specialists agree this would be challenging to implement in primary care at the current time, but this will be signposted to. Committee members noted the desired “Red, Amber, Green, Grey (RAGG)” category being proposed would be Green (initiation in primary or secondary care / non-specialist and specialist initiation) for dapagliflozin and canagliflozin when used for the management of CKD.

A comment was raised recommending using “maximum **licensed** tolerated dose” for ACE-I/ARB titration which is aligned to the NICE TA recommendations and an update to the acknowledgements section to clarify that the CESEL CKD guide aligns to the most current NICE recommendation - NICE TA 775 - as opposed to the NICE guidance on CKD and Type 2 Diabetes Mellitus (T2DM). Members discussed the inclusion of canagliflozin within the CESEL guide for the management of CKD in patients with T2DM, which is in line with the licensing for canagliflozin but not included within the SEL Joint Medicines Formulary for this indication. Committee members agreed by consensus that canagliflozin should be added to the SEL JMF for the management of diabetic kidney disease in line with NICE guidance (NG28).

The costings for the NICE TA on dapagliflozin in CKD had previously been presented in September. In line with the Terms of Reference for the IMOC, as the cost impact exceeded the financial threshold, this was escalated to the Finance and Planning Committee and has been noted and approved by the Finance and Planning Committee.

Committee members approved the medicines section of the CESEL CKD guide and agreed a Green RAGG categorisation (non-specialist and specialist initiation) for the NICE approved, licensed SGLT2 inhibitors, dapagliflozin and canagliflozin, for the management of CKD by consensus pending updates to the CESEL guide in line with the discussions.

ACTION: CESEL Chronic Kidney Disease guide to be updated and progressed for ratification via Chair’s action
ACTION: SEL JMF to be updated with Green RAGG categorisation of dapagliflozin and canagliflozin for the management of CKD

6. Formulary recommendations

New:

- Nystatin for the treatment of early voice prosthesis failure due to candida

Minor comments from the Triage Panel review of the formulary recommendation was shared with Committee members. A comment was shared regarding typographical amendments.

- Rituximab (Rixathon™) injection for the treatment of autoimmune haemolytic anaemia

Comments from the Triage Panel review of the formulary recommendation were shared with Committee members.

Updated:

- Lisdexamfetamine dimesylate (Elvanse Adult®) capsules for attention deficit/hyperactivity disorder (ADHD) in adults
- Dexamfetamine tablets for attention deficit/hyperactivity disorder (ADHD) in adults

Both formulary recommendations have been updated to align with recommendations from the ADHD NICE guidance and the local complex ADHD shared care guideline.

Committee members approved the formulary recommendations pending updates to the new formulary recommendations in line with comments from the Triage Panel review and Committee members.

ACTION: Nystatin and rituximab formulary recommendations to be updated in line with the discussion and ratified via Chair's action.

7. Updated inflammatory bowel disease (IBD) pathway and cost tool

The author was in attendance to present this item, which has been updated via the IBD subgroup. The main update is the inclusion of NICE TA approvals for filgotinib and ozanimod in moderate to severe ulcerative colitis (UC). Committee members noted that in line with NICE cost estimates, the inclusion of filgotinib and ozanimod is not expected to have a significant resource impact as they are substitutions for alternative existing treatments and are similarly priced. The IBD cost tool has also been updated to include filgotinib and ozanimod.

Members also noted that the ferric maltol formulary recommendation will require updating in line with the new recommendation for use in the anaemia management section of the pathway.

Committee members approved the inflammatory bowel disease (IBD) pathway and cost tool by consensus pending the updates as per the discussion.

ACTION: IBD pathway to be updated in line with discussion and ratified via Chair's action
ACTION: Ferric maltol formulary recommendation to be updated and presented at a future IMOC meeting

8. Proposal for the use of an additional single IV dose of ustekinumab in patients with Crohn's Disease on subcutaneous ustekinumab

The author was in attendance to present this item, which has been discussed and approved by the IBD subgroup and recommends the use of a one-off single intravenous (IV) dose of ustekinumab in a small cohort of patients with Crohn's Disease (CD) on subcutaneous (SC) ustekinumab who experience secondary loss of response to treatment.

For this cohort of patients, this intervention could help to re-capture response to therapy before attempting to switch out of therapy class, which tends to be a more costly treatment or surgical intervention. The outcomes from use of ustekinumab in this patient group will be monitored through data reported to the IBD subgroup. The use of one-off single IV ustekinumab dose is considered a low cost and is within the thresholds the Committee is permitted to approve.

A comment was raised in relation to how often the re-induction dose will be used in this patient cohort and whether there will there be an annual limit for re-induction. The author clarified that the proposal only covers the use of a one-off single IV ustekinumab re-induction dose, but this will be taken back to the IBD subgroup for further discussion and consideration.

The Committee approved the use of an additional single IV dose of ustekinumab in patients with Crohn's Disease on subcutaneous ustekinumab by consensus.

ACTION: IBD subgroup to discuss whether there is a limit to the use of additional IV ustekinumab as a re-induction dose

9. Withdrawal of formulary recommendation 066 - clofazimine in combination with clarithromycin and rifabutin as anti-MAP therapy for the treatment of Crohn's disease in adults

The author was in attendance to present this item, which has been discussed and approved by the IBD subgroup. This request is supported by the availability of more advanced clinically and cost effective treatment options for patients with complex Crohn's disease and would result in a Grey RAGG category for the use of anti-MAP therapy in Crohn's disease. Committee members noted that the withdrawal of the formulary recommendation and recategorisation from Red to Grey will not impact those patients who are currently receiving a two year course of anti-MAP therapy, these patients will be able to continue until their course is completed, if clinically appropriate to do so.

The Committee agreed to withdraw the formulary recommendation and a RAGG recategorisation from Red to Grey by consensus.

ACTION: Formulary withdrawal statement to be drafted and presented at a future IMOC meeting
ACTION: SEL JMF to be updated with RAGG recategorisation from Red to Grey for clofazimine in combination with clarithromycin and rifabutin as anti-MAP therapy

10. Formulary recategorisation of sodium zirconium cyclosilicate (Lokelma™) & patiromer for treating persistent hyperkalaemia in CKD stage 3b to 5 or heart failure from Red to Amber 1

The Formulary pharmacist presented this item alongside the applicant, who was in attendance. This formulary recategorisation request is line with the update to NICE TA 599 for Lokelma™ which originally recommended the use of Lokelma™ in secondary care for the treatment of persistent hyperkalaemia. However, NICE TA 599 has been updated to recommend the use of Lokelma™ in primary or secondary care for persistent anaemia. NICE TA 623 for patiromer also does not restrict the use of patiromer to secondary care settings.

Lokelma™ and patiromer enable the maximum licensed tolerated dose of ACE inhibitors (ACEi) and angiotensin receptor blockers (ARBs) to be continued in the presence of hyperkalaemia. The presenters outlined that it would be more beneficial for patient care, access and continuity if this patient cohort could receive their prescription for Lokelma™ or patiromer in primary care. Committee members were requested to consider a RAGG recategorisation from red (hospital only) to Amber 1 (specialist initiation).

A comment was raised that it would be useful to have information for primary care on the use of Lokelma™ and patiromer due to the specific prescribing and patient counselling instructions and regular monitoring of potassium levels required in primary care. The information for primary care could also include how often patients should be reviewed, managing non-adherence and the process for stopping treatment. A comment was also raised in regards to which preparation is used first line, the author confirmed Lokelma™ is used first line and if a patient is unable to tolerate Lokelma™, patiromer is used second line.

GP Committee members raised various concerns in regards to the appropriateness of recategorising Lokelma™ and patiromer from Red to Amber 1, including:

- The black triangle status of Lokelma™ and patiromer and the lack of familiarity with Lokelma™ or patiromer in primary care
- Lack of infrastructure in some SEL boroughs to safely monitor Lokelma™ and patiromer
- The use of Lokelma™ and patiromer in this patient cohort is small and could be managed in secondary care especially as these patients are at the more severe disease end and are seen regularly by the specialist teams.

- Committee members agreed that it would be useful to see patient number and outcome data on the use of Lokelma™ and patiromer in this patient cohort before requesting transfer of prescribing to primary care

Based on the discussion, Committee members agreed that Lokelma™ and patiromer for treating persistent hyperkalaemia in CKD stage 3b to 5 or heart failure should remain as Red (hospital prescribing) by consensus. Data on use in this patient cohort should be presented back to the Committee in 12 months alongside a GP information sheet to support a recategorisation request from Red to an Amber category.

ACTION: Data on the use of Lokelma™ and patiromer to be presented back to the Committee in 12 months
ACTION: GP information sheet to support the prescribing of Lokelma™ and patiromer in primary care to be developed

11. Formulary recategorisation of nifedipine and glyceryl trinitrate (GTN) spray in autonomic dysreflexia in patients with spinal cord injuries from Red to Amber 2

The applicant was attendance to present this item, which requests the Committee to consider the RAGG recategorisation of nifedipine and glyceryl trinitrate (GTN) spray in autonomic dysreflexia in patients with spinal cord injuries from Red (hospital only) to Amber 2 (specialist initiation). On discharge, these patients are provided with an emergency supply of GTN spray or nifedipine to manage their symptoms of autonomic dysreflexia. In the event a patient needs a resupply or their emergency supply goes out of a date, it would be useful if prescriptions could be provided in primary care. Members agreed that there should be consistency in the individual Trust based guidelines on the management of autonomic dysflexia. The applicant confirmed they would be happy to share their guidance.

Committee members agreed the formulary recategorisation of nifedipine and GTN spray in autonomic dysreflexia in patients with spinal cord injuries from Red (hospital only) to Amber 2 (specialist initiation) by consensus.

ACTION: SEL JMF entry for the use of nifedipine and glyceryl trinitrate (GTN) spray in this setting to be updated from Red to Amber 2

12. Standing Items

- Formulary Submissions tracker

Noted

- NICE Technology Appraisal Guidance Summary – ICS attributed medicines & NHSE/I:

The summary was noted and Red, Amber, Green, Grey (RAGG) categories were agreed by consensus.

- London Procurement Partnership (LPP) Pan-London interface prescribing policy (IPP) group Terms of reference – the leads presented an update and shared the minutes from the first two meetings for information with Committee members.

13. Any Other Business:

Committee members were informed that this was the last meeting for the SLaM IMOC representative and thanked them for their contributions and involvement with the Committee since its inception.

IMOC dates for next 3 months

Date	Time	Venue
19th January 2023	2:00pm – 4:30pm	MS Teams
16th February 2023	2:00pm – 4:30pm	MS Teams
16th March 2023	2:00pm – 4:30pm	MS Teams