South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
Thursday 19th October 2023 (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 notes were accepted as an accurate record of the meeting subject to the correction of 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.

4. **Colchicine for the secondary prevention of ischaemic heart disease in adults**

   This formulary submission originates from a Consultant Cardiologist from KCH. The application requests the off-label use of colchicine for the secondary prevention of ischaemic heart disease (IHD) in adults, including after an acute myocardial infarction (MI) and in chronic heart disease. The application requests prescribing is continued in primary care after specialist initiation.

   - **Evidence review**

   The Formulary Pharmacist provided an overview of the efficacy evidence for the use of colchicine in this setting. A detailed evidence review was provided within the meeting agenda pack. The information presented also included the estimated resource impact for colchicine in this setting. The resource impact of the submission is within the financial threshold that the Committee is authorised to approve.

   - **Applicant's presentation**

   The applicants were in attendance to present the submission and field any questions. The applicant's declaration of interest form was noted. The applicants clarified that the request for colchicine in this setting is for the secondary prevention of IHD in high risk patients with established coronary artery disease or post myocardial infarction (MI), which is in line with the two main trials.

   A comment was raised in relation to the impact of adding colchicine to the current regimen of medicines patients in this cohort are recommended to take and the impact on increased polypharmacy and reduced patient compliance. The presenters clarified the team has developed a patient booklet to support patients in understanding the benefits and risks of their medication and the need to balance the polypharmacy against the reduction in the risk of major adverse cardiovascular events (MACE). Comments were raised in relation to the criteria for use for colchicine in this setting, the presenters clarified colchicine will be beneficial in patients who are young, experience recurrent acute coronary syndrome and have lower low density lipids (LDLs) in relation to their event rate. The United States (US) recommends colchicine for patients at very high risk of experiencing another cardiovascular disease (CVD) event despite treatment with maximum tolerated standard treatment. However the European Society of Cardiology (ESC) guidelines are less prescriptive and this is also being taken into consideration in regard to the local criteria for use.

   The follow up arrangement for patients initiated on colchicine in this setting was also raised by Committee members. The presenters clarified follow up will vary across the SEL Trusts, however all patients will be provided with 3 months' supply on discharge. As side effects with colchicine tend to occur within the first 3 months, patients are reviewed at their Trust at 3 months, the cardiology team will be able to confirm continuation followed by transfer of prescribing to primary care or discontinuation of treatment. All SEL Trusts could not confirm similar arrangements for follow up.

A comment was raised in relation to the whether patients will be optimised on treatment in line with guidance from the National Institute for Health and Care Excellence (NICE) before colchicine is initiated. The presenters clarified patients will be managed in line with treatment options as per NICE guidance, however colchicine may be initiated in parallel. It was recognised initiating colchicine in parallel whilst optimising established treatments is outside of the ESC guidance. The presenters confirmed patients would not be managed outside of ESC guidance, however there will be instances where colchicine may be beneficial in parallel to nationally recommended treatment options, for example patients who can only tolerate 40mg high intensity statin despite recommendation to be on 80mg and are not reaching target LDL levels. Comments were also raised regarding the lack of ethnically diverse participants in the trials and the resulting applicability of the data, especially in view of the higher prevalence and impact of CVD in some ethnic populations.

Primary care members present at the meeting acknowledged familiarity with prescribing colchicine, however, in this off-label setting, there is no experience of use. In line with the associated side effect profile with colchicine, the unknown long-term safety profile in this patient group and lack of national guidance, transfer of prescribing to primary care would not be appropriate currently. It would be more appropriate to retain prescribing within the hospital services and review outcome and safety data in a years' time when further studies may also be available.

- **IMOC discussion after departure of the applicant**

Committee members discussed the application and members acknowledged that whilst there is a signal that colchicine is beneficial to patients at very high risk of experiencing secondary CVD events, there is concern from GP members regarding the long term use and the lack of experience of this in primary care, especially in potentially large numbers of patients. Committee members also shared concerns in relation to consistency in the follow up criteria across all SEL Trusts and the lack of clarity regarding robust criteria for use, which currently covers a broad population and does not seem to follow ESC guidance.

Committee members agreed by consensus a time limited approval under a Red, Amber, Green, Grey (RAGG) category of Red (hospital only), with a caveat for outcome data to be presented back to the Committee at a future meeting. The applicants should also be encouraged to raise this with NICE. Further discussions will take place outside of the meeting to agree specific criteria for use with the applicants.

Post meeting note: The KCH formulary pharmacist has liaised with the applicant to request agreed criteria for use of colchicine in this setting alongside the criteria for the outcome data. This will be discussed and agreed at the next IMOC meeting.

ACTION: Formulary recommendation to be drafted and presented at a future meeting
ACTION: Outcome data to be presented back to the Committee at a future meeting (time frame to be agreed)

5. Recategorisation proposal for bempedoic acid from Amber 2 to Green for primary hypercholesterolaemia or mixed dyslipidaemia (includes monotherapy)

The author presented this item and outlined that bempedoic acid is recommended locally in combination with ezetimibe in line with NICE technology appraisal (TA) 694 as an option for treating primary hypercholesterolaemia or mixed dyslipidaemia if statins are contraindicated or not tolerated or ezetimibe alone does not control LDL levels well enough. Bempedoic acid monotherapy is also recommended locally, in line with the product licence. Bempedoic acid has been in use across SEL for approximately 2 years.

Committee members were requested to consider a recategorisation for bempedoic acid with ezetimibe and bempedoic monotherapy from Amber 2 (specialist initiation) to Green (primary or secondary care initiation) to improve patient access and outcomes. A frequently asked question (FAQ) will be developed for primary care to support the safe and appropriate prescribing of bempedoic acid.

Some GP members felt that an Amber 1 category would enable GPs to be more supported and seek specialist advice and guidance before initiating. The presenter clarified the Green categorisation would still enable primary care clinicians to seek specialist advice and guidance where required. However it would also enable those GPs who feel confident to initiate bempedoic acid in primary care to do so in line with local guidance and supporting resources, which will prevent the delay patients are currently experiencing with the specialist lipid clinics. The FAQ will also support primary care clinicians alongside education and training sessions.

An additional comment was raised regarding the lipid lowering effect of bempedoic acid monotherapy, which is lower than high intensity lipid treatment, in line with this it would be preferable to recategorise the use of bempedoic acid with ezetimibe to Green and monotherapy to Amber 1. The presenter clarified that although the LDL lowering potential of bempedoic monotherapy is less than the 40% target, there are outcome data from studies which demonstrate that bempedoic monotherapy will reduce cardiovascular risk which is beneficial in patients who are unable to tolerate a statin or ezetimibe. Committee members noted it may be confusing having two different categories for the same medication with the same indication. However to prevent treatment delay in patients who could benefit from treatment with bempedoic acid with ezetimibe a Green categorisation would be favourable and an Amber 1 category for bempedoic monotherapy which is used less often in a smaller patient cohort. The advice and guidance route could be used to obtain specialist input for initiation in the monotherapy setting.

Committee members agreed by consensus the recategorisation of bempedoic acid with ezetimibe from Amber 2 (specialist initiation) to Green (primary or secondary care initiation) and for bempedoic monotherapy a recategorisation from Amber 2 to Amber 1 (initiation in primary care on advice of a specialist). Members agreed that a further review of the Amber 1 status in monotherapy could be considered in 6 months.

ACTION: Recategorisation of bempedoic acid/ezetimibe to Green and bempedoic acid monotherapy to Amber 1 be added to the SEL JMF

6. SEL Acute Provider Collaborative (APC) adult ear, nose, and throat (ENT) primary and secondary care interface guidelines – approval of the medicines content

Colleagues from the SEL APC were in attendance to present this item. The guideline covers the following set of common ENT conditions seen in primary and secondary care: ear wax, foreign body (ear or nose), otalgia, membrane perforation, ear discharge and otitis externa (acute and chronic), otitis media, hearing loss, vertigo, tinnitus, eustachian tube dysfunction, sinusitis, nasal congestion, allergic rhinitis, nasal polyps, epistaxis, snoring, altered smell, sore throat, swallowing issues, neck lump and Bell's Palsy.

The guidelines were circulated for consultation with the IMOC and for broader consultation to all GP practices in SEL and the Local Medical Committee (LMC). The presenters informed Committee members that additional updates have been made to the guideline following dissemination of the IMOC agenda pack in the nasal polyp's section.

Committee members were informed that for antibiotic recommendations, the different sections in the ENT guideline direct users to "local antibiotic guidelines" or NICE guidelines instead of making specific recommendations. There is a piece of work underway through the SEL antimicrobial stewardship network to harmonise the different antibiotic guidelines across the 6 SEL boroughs via an online platform. Once complete the APC ENT guideline authors have confirmed that they will update the guidelines to incorporate links to the online platform as relevant.

A comment was raised in relation to the use of Naseptin™ within the epistaxis section which is off-label, although a recognised use in this indication, is not on the formulary. Committee members agreed by consensus the addition of Naseptin™ to the local formulary for the management of epistaxis. A comment was also raised regarding the foreign body of the ear or nose section – for cases where button batteries have been swallowed, it was queried whether, in addition to calling 999, the use of 10mls honey should be added to decrease risk of oesophageal burns. The presenters agreed to follow

this up. Members were asked to note that in view of time, some further minor comments, related to formatting would be shared with the presenters after the meeting.

Committee members approved the medicines content of the SEL APC adult ENT primary and secondary care interface guidelines by consensus pending amendments in line with the discussion.

ACTION: Guideline to be updated and returned to the IMOC team to progress for ratification via Chair's action
ACTION: Naseptin™ for the off-label use in the management of epistaxis to be added to the SEL JMF

7. Planned actions developed by the primary care sub-group of the SEL Forum for Antimicrobial Stewardship (SEL FAS) to support activities during World Antibiotic Awareness Week

The borough Medicines Optimisation lead presented this item, which outlines a series of actions/resources developed by members of the SEL FAS for engagement within SEL for World Antimicrobial Stewardship Awareness Week (WAAW) occurring in November. This includes a crib sheet document which includes the most up to date resources in relation to antimicrobial stewardship including access to webinars, guidelines, and protocols. The presenter was requested to report back on an evaluation of the outcomes from delivering the WAAW action plan at a future IMOC meeting.

Committee members noted the planned actions to support activities during World Antibiotic Awareness Week.

ACTION: Evaluation and feedback from activities undertaken during WAAW to be presented back to Committee

8. Updates from South East London Forum for Antimicrobial Stewardship (SEL FAS):
- **SEL FAS Terms of Reference (ToR)**
- **COVID-19 treatments monitoring framework**

The author was in attendance to present this item. Committee members noted the SEL FAS Terms of Reference (ToR) and a minor typographical error highlighted.

As the transfer of funding arrangements for COVID-19 treatments moved from NHS England to Integrated Care Boards in April 2023, an outcomes and monitoring framework has been developed to outline the parameters that will be measured in the interim whilst the service delivery model for COVID-19 medicines is reviewed and finalised.

Committee members approved the SEL FAS Terms of Reference and COVID-19 treatments monitoring framework by consensus.

9. Formulary recommendation 146 – Alimemazine for the management of dystonia particularly with poor sleep and/or vomiting in paediatrics.

This formulary recommendation has been drafted following consideration of the formulary application for the use of alimemazine in this setting at the September IMOC meeting. The formulary recommendation is for the agreed red RAGG category and is a time limited approval for a year to enable outcomes to be presented back to the Committee. A revised version was shared on screen as the version in the agenda pack has been updated following comments from the Triage Panel review.

Committee members approved the formulary recommendation by consensus.

10. Updated shared care guideline template

The borough medicines optimisation lead presented this item which has been updated via the Shared Care Task and Finish group. The main updates to the shared care template were noted by Committee members.

Committee members approved the updated shared care guideline template by consensus.

11. Updated inflammatory bowel disease (IBD) treatment pathway and associated resources:

- **IBD treatment pathway**
- **IBD pathway cost tool**
- **IBD pathway outcomes and monitoring pathway**
- **Dose escalated anti-TNF therapy criteria for use**
- **Dual biologic therapy criteria for use**
- **NICE TA 905: upadacitinib for previously treated moderately to severely active Crohn's disease – local cost modelling for SEL and NICE resource impact report**

A member of the IBD sub-group of the IMOC was in attendance to present this item, which has been updated and approved via the IBD sub-group. The main updates to the IBD treatment pathway include addition of upadacitinib for the management of ulcerative colitis (UC) in line with NICE TA 856 and in Crohn's disease (CD) in line with NICE TA 905 and risankizumab for the management of CD in line with NICE TA 888. The IBD pathway cost tool has also been updated to include the new NICE TA approved treatment options.

The NICE resource impact statement for upadacitinib in UC and risankizumab in CD is not anticipated to be significant resource impact as it is a further treatment option for this patient cohort and the cost is likely to be a substitution. However for upadacitinib in CD, the Committee noted the estimated cost impact over time exceeds the delegated authority for the SEL IMOC to approve. In line with the Committee Terms of Reference, the cost impact at steady state in year 5 exceeds the agreed financial threshold. This will be escalated to the ICB Executive Committee. As this is a NICE TA, which the NHS is legally obliged to implement, the cost impact will be shared with the Executive Committee for information only.

Committee members noted that the use of upadacitinib in CD also provides a cost saving across three years in service delivery related costs as upadacitinib is more cost effective in comparison to treatments such as ustekinumab and vedolizumab as less infusion suite appointments will be required.

The IBD pathway outcomes and monitoring framework has been updated to include the monitoring of second line biologic treatment in UC and CD as well new locally commissioned elements of the pathway (dual biologic therapy in CD). The criteria for use for the use of escalated anti-TNF dosing in CD and dual biologics used in CD, have been updated to include a response criteria which involves an assessment at 6 months to assess disease activity rather than a physician's global assessment.

Committee members approved the updated IBD treatment pathway and associated resources by consensus.

ACTION: Estimated cost impact for upadacitinib in CD to be escalated to the Executive Committee for information

12. Updated shared care guideline for paliperidone long-acting injection – updated to incorporate 6-monthly preparation

The leads for this guideline presented this guidance which has been updated to incorporate the 6-monthly preparation (Byannli™). Updates to the shared care guideline include the prescribing and administration information for Byannli ™.

Committee members approved the updated shared care guideline for paliperidone long-acting injection by consensus.

13. Standing items

- Formulary submissions tracker

Noted.

- NICE Technology Appraisal (TA) Guidance Summary - ICS & NHSE/I attributed medicines:
  - The summary was noted and Red, Amber, Green, Grey (RAGG) categories were agreed by consensus.
- For information and noting
  - Paediatric formulary updates
  - Resources to support practices in managing the shortages of GLP-1 receptor agonists, approved via the urgent Triage Panel process on 3rd October 2023 (available via the SEL IMOC webpages)

These were noted by Committee members.

14. Any Other Business

Nil items raised.

IMOC dates for next 3 months

Date	Time	Venue
16th November 2023	2:00pm – 4:30pm	MS Teams
14th December 2023	2:00pm – 4:30pm	Hybrid – MS Teams/in person
18th January 2024	2:00pm – 4:30pm	MS Teams