South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
15 May 2025 (Online via MS Teams)
Final Minutes

1. Welcome, introductions and apologies

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

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. A declaration was noted from the presenters of agenda item 5 - guidance for the use of continuous glucose monitoring in Type 2 diabetes, formulary requests and associated cost modelling. No further conflicts were raised by members.

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 the progress against actions due for this month, these were noted, and items closed were agreed. In relation to an action from March 2025 on the implementation of guidance from the National Institute for Health and Care Excellence (NICE) on tirzepatide (Mounjaro®) and semaglutide (Wegovy®) for weight management in SEL, committee members were informed a revision to the cost modelling originally presented in March 2025 had been made. The cost modelling has been updated by leads to reflect the cohorts in the recently published NHS England commissioning statement. In line with this, the updated cost modelling was escalated to the Executive Committee rather than the cost modelling presented in March 2025.

4. Formulary request for medicines used to treat migraine in paediatrics (historical additions) and associated evidence review:

- **Sumatriptan, zolmitriptan and rizatriptan for the acute management of migraine**
- **Pizotifen, flunarizine and amitriptyline for the prophylactic management of migraine**

The applicants were in attendance to present this item with support from the Formulary Pharmacist. This is a formulary request based on historical use, with some of the treatments recognised within the British National Formulary for Children (BNFc) and NICE clinical guideline 150 (CG150) on the management of headaches in people aged over 12 years old. The proposed medicines for inclusion within the formulary for the acute and prophylactic management of migraine are:

Acute treatment (off-label use)

- Sumatriptan tablets as Green (*first line oral treatment, 6 years old and above)*
- Sumatriptan nasal spray as Amber 1 *(first line non-enteral treatment option, 6 years old and above)*
- Sumatriptan subcutaneous injection as Amber 1 *(third line non-enteral treatment option, 10 years old and above)*
- Zolmitriptan orodispersible tablets as Amber 1 *(second line oral treatment, 12 years old and above)*
- Zolmitriptan nasal spray as Amber 1 *(second line non-enteral treatment option, 12 years old and above)*
- Rizatriptan orodispersible tablets as Amber *1 (second line oral treatment, 6 years old and above)*

Prophylactic treatment (all requested as “Red, Amber, Green” (RAG) category amber 1)

- Pizotifen tablets *(first line, 5 years old and above, licensed)*
- Amitriptyline tablets and liquid *(second line, 6 years old and above, off-label)*
- Flunarizine tablets and capsules *(third line, 5 years old and above, off-label and unlicensed formulation)*

There is also a request to recategorise topiramate tablets, capsules and liquid which are already on the formulary for the prophylactic treatment of migraine from Green to Amber 1 *(12 years old and*

above). Propranolol capsules, tablets, and liquid is also on already on the formulary for the prophylactic treatment of migraine as Amber 1 (*2 years old and above)*.

The Formulary Pharmacist provided a brief overview of the evidence to support the formulary inclusion request for rizatriptan, amitriptyline and flunarizine, as these treatments are not within nationally recognised guidance or have established use and are off-label in this setting. Rizatriptan is licensed for the acute treatment of migraine in adults and amitriptyline is licensed for the prophylactic treatment of chronic tension type headache in adults. Flunarizine is a calcium channel blocker that reduces arterial and arteriolar smooth muscle spasm, and is unlicensed in the UK, but licensed in other countries for the prophylaxis of migraine in adults aged 18 years and older.

Rizatriptan is approved by the US Food and Drug Administration for acute treatment of migraine, with or without aura, in adults and children aged 6-17 years. The pivotal licensing study was a double-blind, placebo-controlled randomised controlled trial (RCT) and which included 1,382 participants aged 6-17 years old with poor response to NSAIDs or paracetamol. The primary efficacy endpoint was pain freedom at 2 hours in 12–17-year-olds. For the primary outcome, rizatriptan demonstrated a statistically significantly higher response rate than placebo. Rizatriptan was generally well tolerated, and incidences of adverse events, drug-related adverse events, and triptan-related adverse events were generally comparable between rizatriptan and placebo across the different age groups.

Studies of amitriptyline for migraine in children are limited, and treatment is supported mainly by data in adults. A large RCT comparing amitriptyline, topiramate and placebo for migraine included 361 children and adolescents aged 8 -17 years with migraine, with or without aura. The primary outcome was a relative reduction of 50% or more in the number of headache days in the comparison of the 28-day baseline period. The trial was however concluded early due to ineffectiveness after a planned interim analysis. The interim analysis found no significant difference between groups in the primary outcome and there was no significant difference in effect when the two active drugs were compared with each other. Patients who received amitriptyline or topiramate had higher rates of several adverse events than those receiving placebo. The authors concluded that given the null outcome, and adverse events reported in the amitriptyline and topiramate groups, the data do not show favourable risk-benefit profile for the use of these therapies in paediatric migraine prevention.

In 2014 NICE produced an evidence summary of flunarizine for migraine prophylaxis due to the potential clinical impact of long-term prescribing in primary care, which included a Cochrane review (2003) and four studies. Only the Cochrane review investigated use in children. The Cocrane review identified 2 RCTs that compared flunarizine with placebo and 4 RCTs that compared it with an active comparator. Headache frequency standardised over 28 days was used as the primary outcome measure. A 12-week, double-blind RCT with 48 children and young people aged 7 to 14 years compared flunarizine 5 mg daily with placebo. Flunarizine was shown to statistically significantly reduce migraine frequency compared to placebo. The second RCT was a crossover study with 70 children aged 5 to 11 years old and found that headache frequency was statistically significantly lower with flunarizine than with placebo after 2 and 3 months of treatment. The review of the 4 RCTs that compared flunarizine with an active comparator, including propranolol, aspirin, nimodipine, and dihydroergotamine found there was no statistically significant difference between flunarizine and the other treatments for reduction in migraine frequency. No new safety signals were identified from the trials included in the Cochrane review, and commonly reported adverse events included sleepiness and weight gain.

From a resource perspective the cost impact of this formulary request is within the financial threshold delegated to the committee. As this is a historical request and in view of existing current practice, the use of the migraine agents outlined in this request is not expected to be an additional cost.

A query was raised regarding whether there are any clinical symptoms patients display which enables clinicians to decide a more potent triptan such as rizatriptan is preferred as a second line

triptan treatment instead of zolmitriptan. The presenter clarified that the choice between triptans is often based on clinician preference and the patient's response to initial treatment. In patients where the effects of sumatriptan have diminished or they have had a partial response, rizatriptan is often a suitable triptan to trial next. A comment was raised in relation to the use of amitriptyline for migraine prophylaxis as a second line treatment in patients who may experience poor sleep and mood disturbance associated with the migraine and whether there are any other clinical scenarios where amitriptyline would be the preferred second line treatment option instead of topiramate. The presenter explained there has been an increase in the second line use of amitriptyline in this setting in comparison to topiramate due to the recent MHRA pregnancy prevention measures associated with topiramate.

A query was raised in relation to whether propranolol or pizotifen is used more as a first line prophylactic treatment in this setting as in practice pizotifen has often caused drowsiness and weight gain in patients. The presenter explained, as asthma tends to be quite common in paediatrics, propranolol is not suitable in this patient cohort. However, if there are no other clinical concerns, propranolol is often used first line. Using pizotifen in the evening can help with the drowsiness and the weight gain associated with pizotifen can be a concern in adolescents, however, this is not usually a reason for not prescribing pizotifen first line.

A comment was raised in relation to categorising sumatriptan as Amber 1 as opposed to the proposed category of Green, which enables one RAG category for the triptans recommended in this setting. GP committee members noted the prescribing of sumatriptan in older children with a definitive diagnosis of migraine in primary care is appropriate and aligns to the proposed Green category. However, for younger children, without specialist input, the initiation of sumatriptan in primary care is unlikely. Committee members agreed, if approved, sumatriptan with a RAG category of Green is appropriate but the formulary should note that for younger children advice and guidance should be sought prior to initiation.

Committee members approved the following by consensus:

- The formulary inclusion of the following triptans for the acute treatment of migraine in paediatrics:
  - Sumatriptan tablets as Green
  - Sumatriptan nasal spray and subcutaneous injection as Amber 1
  - Zolmitriptan orodispersible tablets and nasal spray as Amber 1
  - Rizatriptan orodispersible tablets as Amber 1
- The formulary inclusion of the following treatments for the prophylactic treatment of migraine in paediatrics:
  - Pizotifen tablets as Amber 1
  - Amitriptyline tablets and liquid as Amber 2
  - Flunarizine tablets and capsules as Red
- Recategorsation of topiramate for the prophylactic treatment of migraine in paediatrics from Green to Amber 2
- Propranolol for the prophylactic treatment of migraine in paediatrics to remain as Amber 1

Members also agreed that to support primary care prescribers to prescribe safely, detailed formulary entries will be required for each medication which includes place in therapy, initiation & stopping criteria, and any monitoring requirements, in place of a guideline being developed.

ACTION: Detailed formulary entries for sumatriptan, zolmitriptan, rizatriptan, pizotifen, propranolol, amitriptyline, topiramate and flunarizine to be drafted and presented at a future meeting for approval

5. Guidance for the use of continuous glucose monitoring (CGM) in Type 2 diabetes (T2DM), formulary requests, and associated cost modelling

The authors were in attendance to present this item on behalf of the diabetes sub-group. In line with updated NICE guidance on the use of continuous glucose monitoring (CGM) in people living with type 2 diabetes (T2DM), pregnant people living with T2DM and children and young people (CYP)

living with T2DM, pan-London guidance to support the implementation of CGM in people living with T2DM has been developed. The guidance was developed by representatives from the diabetes sub-group and colleagues across London to develop consistent guidance on the use of CGM in T2DM. The pan London CGM implementation guidance is based on legacy eligibility criteria and guidance, NICE guidance and NHS England (NHSE) recommendations and was consulted on across SEL

The pan-London CGM implementation guidance recommends the following cost-equivalent CGM devices (available on FP10 prescription) in this setting:

- Dexcom ONE +®
- Freestyle Libre 2 Plus®
- GlucoRx Aidex®

Where these CGM devices are not clinically suitable, in line with NICE and NHSE guidance, use of supply chain CGM devices can be considered for children and young people living with T2DM and in pregnancy in T2DM.

In view of the publication of the pan-London CGM implementation guidance, committee members were requested to approve the local adoption of the pan-London guidance and the formulary inclusion of Dexcom ONE +®, Freestyle Libre 2 Plus® and GlucoRx Aidex® with a Green RAG category. For complex T2DM patients eligible for CGM, it is recognised that the initiation of CGM in these patient cohorts will be via a specialist as opposed to primary care. Committee members noted that the approval of the pan-London guidance includes approving the use of NHS supply chain (hospital only) devices for the small cohort of patients where CGM FP10 devices are not suitable. The approval of these devices is not usually within the remit of the committee as they are not prescribable on FP10. However, in the interest of a consistent approach to the implementation of CGM in this setting, on this occasion the committee is being requested to approve the use of NHS supply chain CGM devices in line with the pan-London guidance. No objections were raised by committee members on this point.

From a cost perspective, based on cost modelling from NICE, the implementation of the CGM devices in this setting will be phased over a 5 year time period. As the estimated cost impact associated with the pan-London CGM implementation guidance is above the financial threshold delegated to the committee, the cost modelling will need to be escalated to the Executive Committee for financial approval. In line with this, the committee can only approve the clinical aspects of the pan-London CGM implementation guidance for local adoption and the formulary inclusion of Dexcom ONE +®, Freestyle Libre 2 Plus® and GlucoRx Aidex® (proposed as Green).

In line with the request to locally adopt the pan-London CGM implementation guidance, committee members were requested to approve the retirement of the local guidance and supporting documents for FreeStyle Libre 2 (FSL2). As the local FSL2 guidance and supporting documents cover the use of CGM in CYP living with Type 1 diabetes (T1DM) but is not in line with updated national guidance, committee members were also requested to approve the use of an interim statement in place of the FSL2 guidance and supporting documents on the SEL IMOC diabetes webpage.

As a result of the planned discontinuation of FSL2 sensors in August 2025, the paediatric joint formulary requires an update to include the new FSL2 sensor - FreeStyle Libre 2 Plus (FSL2 Plus) to ensure continual access to FSL for CYP living with T1DM. Whilst an abridged formulary request has not been provided, committee members were asked to also consider approving the inclusion of FSL2 Plus to the paediatric joint formulary. The presenters noted that FSL2 Plus is an upgraded version and the current version will be discontinued in the very near future. Committee members were informed there is no additional cost impact from the formulary inclusion of FSL2 Plus in place of FSL2. Committee members supported the inclusion of Freestyle Libre 2 Plus in the SEL Paediatric Formulary for CYP with T1DM by consensus.

GP Committee members raised that an Amber 1 categorisation may be more suitable for the use of CGM in this setting. Many GPs without a specialist interest in diabetes have not received the appropriate education and training to appropriately initiate CGM in primary care. The presenters clarified that the Green categorisation request is in line with the Green category for blood glucose

meters which are being replaced for CGM devices in this patient cohort. The pan-London CGM implementation guidance includes links to training and education for primary care clinicians and the CGM devices are straightforward for patients to use with many patient resources also. The presenters also noted that there is primary care data available demonstrating that CGM devices are already being prescribed in this setting which indicates GPs are comfortable with prescribing CGM devices in primary care. The presenters also noted that an Amber 1 categorisation for the use of CGM devices in this setting could cause a delay in access to CGM devices for patients and drive patients who are predominately managed in primary care to secondary care where there are existing capacity issues.

In response GP Committee members explained this is likely GPs with a specialist interest in diabetes. As CGM devices have been historically initiated by specialists, there is a skill gap for most GPs/primary care prescribers as they do not have a specialist interest in diabetes.

Concerns were raised regarding the initiation of CGM devices in primary care for high risk patients. The presenters clarified that most of the patients eligible for CGM devices in this setting will be under the care of a specialist for the management of their diabetes and the initiation of CGM in complex patients will be by the specialist team.

Committee members approved the following by consensus:

- Local adoption of the pan-London CGM implementation guidance (clinical content only), including the approval of NHS supply chain CGM devices in CYP and pregnant people with T2DM where CGM FP10 devices are not suitable.
- Formulary inclusion of Dexcom ONE +®, Freestyle Libre 2 Plus® and GlucoRx Aidex® as Amber 1 *(initiation in primary care on the advice of a specialist or GP with a specialist interest in diabetes)* for the management of T2DM in adults, children and young people and pregnant people
- Retirement of the local guidance and supporting documents for FreeStyle Libre 2; replaced with an interim statement in relation to the pan-London guidance underway for the use of CGM in CYP living with T1DM
- Formulary inclusion of FreeStyle Libre 2 Plus for CYP living with T1DM.

ACTION: Estimated resource impact based on NICE modelling to be escalated to the Executive Committee for approval
ACTION: Retirement of local guidance and supporting documents for FreeStyle Libre 2 and replaced with an interim statement for CGM in CYP living with T1DM
ACTION: Dexcom ONE +®, Freestyle Libre 2 Plus® and GlucoRx Aidex® to be added to the local adult and paediatric formularies for the management of T2DM in adults, CYP and pregnant people as Amber 1 following financial approval and publication of interim statement
ACTION: FreeStyle Libre 2 Plus to be added to paediatric formulary for CYP living with T1DM

6. Outcome data on the use of rituximab for the treatment of refractory autoimmune hepatitis in adults (review of time limited approval)

The author was in attendance to present this item following the formulary application approval in April 2023 which requested the presentation of outcome and safety data for the use of rituximab in this setting over a phased timeframe. At KCH over the last 2 years, four SEL patients have been initiated on rituximab in this setting and no patients at GSTT. The report enclosed in the agenda pack was presented. Overall, all four patients were treated in line with the formulary recommendation and two achieved a biochemical response to treatment. No concerns were identified in relation to adverse effects for the four patients treated. It was also noted that one patient was able to reduce their steroid dose as a result of treatment with rituximab and another patient managed to stop their steroid treatment altogether.

The number of patients treated was significantly lower that the number estimated in the original application, which estimated 15 patients per annum across SEL.

As comment was raised regarding the availability of the next set out of outcome data to be presented to the committee which is in relation to longer term outcomes associated with the use of rituximab in this setting, for example prevention of cirrhosis, liver failure, and progression to liver transplantation. This outcome data was estimated to become available from year 5 onwards, however due to the low patient numbers over the last 2 years, it was queried whether the longer term outcome data would be available by year 5. The presenter explained data is being collated across the UK and Europe in relation to the use of rituximab in this setting with the autoimmune hepatitis group and would be happy to present the longer term outcome data from this database to the committee in the future.

Committee members noted the outcome data and agreed by consensus to remove the time limit associated with the formulary approval.

ACTION: Formulary recommendation to be updated and approved at a future IMOC meeting

7. Cariprazine outcome data for the treatment of schizophrenia in adults

The authors were in attendance to present this item following the presentation of outcome data for the use of cariprazine in this setting in May 2023 which requested further outcome data to be presented in 2 years. A slide deck summarising the report in the agenda pack was presented on screen, the main highlights from the report summarising the outcome data for patients initiated on cariprazine for the management of schizophrenia between June 2023 – April 2025:

- Across SEL 70% of patients were initiated on cariprazine in line with the formulary recommendation
- In terms of the clinical outcomes, 56% of the patients who continued treatment for at least six months had a follow up Scale for the Assessment of Negative Symptoms (SANS) score completed. There was a reduction in the SANS score from the mean baseline score of 66 to 25 after six months and 27 after 12 months which would be classified as treatment response
- Patients who did not have follow up SANS score reasons included patients lost to follow up
- The number of hospital bed days before cariprazine treatment was 50.4 days in comparison to 35.8 days after cariprazine treatment was initiated
- The most reported adverse effects included akathisia and acute movement disorders
- Majority of patients initiated on cariprazine received regular review by the specialist mental health team following the transfer of prescribing to primary care.

A query was raised in relation to patients who did not have a follow up SANS score at 6 months and 12 months following the initiation of cariprazine and whether treatment is stopped in these patients. The presenter explained treatment is continued if a response to treatment has been observed and there is no relapse in their schizophrenia despite the lack of a follow up SANS score from baseline.

A comment was raised regarding a review of the formulary recommendation in relation to the existing cariprazine continuation criteria versus how cariprazine is reviewed and continued in practice, as many patients are continued on cariprazine outside of the formulary recommendation criteria for use. The presenter agreed to update the clinical outcomes table within the outcomes report to demonstrate whether cariprazine treatment was continued or discontinued based on the review of SANS score.

Committee members noted the outcomes report and agreed by consensus that presentation of an updated outcomes report which demonstrates whether cariprazine was continued or discontinued following a review of SANS score would be useful for the committee to review. Committee members also agreed by consensus that the specialist mental health team should review how cariprazine is reviewed and continued in practice, in comparison to the formulary recommendation continuation criteria, and report back to the committee.

ACTION: Updated outcomes report to be presented at a future meeting

ACTION: Review of the cariprazine continuation criteria in practice versus the formulary recommendation continuation criteria and present at a future meeting

8. SEL IMOC Workplan 2025/26

A member of the SEL IMOC support team presented this item covering the proposed workstreams for the SEL IMOC in 2025/26 workplan. The committee membership was informed that in line with the ongoing NHS organisational changes including within the Integrated Care Board (ICB), the IMOC workplan for 2025/26 is a simplified workplan with 4 main focus areas, relating to improving efficiency in the committee's processes.

Committee members approved the SEL IMOC workplan for 2025/26 by consensus

9. Update on the change programme for SEL Integrated Care Board

The committee received an update from the ICB Chief Pharmacist on the organisational change process underway in ICBs and what the new functions of ICBs are expected to be following the reforms announced in March 2025. In line with the recently published model ICB blueprint, ICBs will have a greater focus on strategic commissioning, population health and reducing health inequalities. Consequently, ICBs have been mandated to review and reduce their running costs to £18.76 per head of population by Q3 2025/26

A letter from the ICB Chief Pharmacists across England has been sent to the NHSE interim Chief Executive which highlights the importance and impact of medicines and requesting a discussion regarding how this will be managed during the rapid transition of the change programme. There will be a Medicines Optimisation (MO) function in strategic commissioning, however, some of the functions currently carried out by the MO teams will transfer over to providers over time. The detail in relation to which functions of the MO teams will be transferring to providers is still to be determined.

In terms of SEL IMOC, changes may include exploring ways of working on a regional or national level for some areas medicines/pathways. Providers will need to take on a more prominent system delivery role as ICBs will be running at a much smaller scale.

Committee members noted the update on the change programme for SEL ICB and acknowledged it is a challenging time across the NHS which may potentially change the operation and functions of the committee. Further updates will be provided as the organisational change programme progresses and evolves.

10. Standing items/Items for information only

- Formulary submissions tracker/ NICE TAs

Noted.

- NICE Technology Appraisal (TA) Guidance Summary – ICS & NHSE attributed medicines:

The summary was noted, and RAG categories were agreed by consensus, where it was possible to confirm the RAG status.

- For information and noting:
- SEL interim policy statement for prescribing Wegovy® and Mounjaro® for weight management on the NHS in SEL and associated patient communication
- Updated pan-London "Red, Amber, Green" definitions
- The following updated documents were approved via IMOC Chair's action without presentation at a committee meeting following minor updates:
    - Paediatric vitamin D guideline (minor updates made including the addition of new preparations following shortages)
    - Hypoglycaemia guideline for type 2 diabetes, once daily basal injections, and sick day rules (extension to review dates)
    - GLP -1 information sheet and pathway (minor updates to reflect the resolution of GLP-1 shortages)

- Formulary recommendation 147 - Colchicine in ischemic heart disease (minor update to extend time limited approval)
- Guidance on alternatives to prescribing unlicensed specials in primary care (minor update in line with changes to recent guidelines and formulary updates)

Committee members noted these updates.

IMOC dates for next 3 months

Date	Time	Venue
Thursday 19th June 2025	2pm – 4:30pm	MS Teams
Thursday 17th July 2025	2pm - 4:30pm	MS Teams
Thursday 21st August 2025	2pm – 4:30pm	Hybrid in person/MS Teams