South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
16th March 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 action notes and minutes were accepted and approved as an accurate record pending 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. Lipid management summary guide

The author was in attendance to present a summary of the broader lipid management pathways. The summary is intended to support the implementation of the full lipid management guidance in primary care. The detailed information regarding lipid management across primary and secondary care remains in the full lipid management pathway.

Comments were raised regarding the inclusion of additional information within the summary guide such as the inclusion of a statement which advises that rosuvastatin doses greater than 40mg requires specialist supervision and making clear that the initiation of specialist treatment options (including the injectable treatments) should be via a lipid specialist.

Committee members approved the lipid management summary guide by consensus pending the requested amendments as per the discussion.

ACTION: Lipid management summary guide to be updated in line with discussion and progressed for Chair's action

5. Long-acting antipsychotic injections (LAI) - update on primary care project

The project lead was in attendance to update the Committee on progress with this initiative, which follows on from the results of a primary care survey previously discussed at the July 2022 IMOC meeting. Following the actions and next steps identified from the survey, discussions with local primary care clinicians occurred to understand the barriers to prescribing LAIs in primary care. In terms of next steps, the plan is to create a pathway that covers both primary and secondary care and identify practices to implement a pilot. Options such as providing a dedicated pharmacy led telephone or email contact and including specialist mental health pharmacists at annual reviews are also being explored.

The project leads were thanked for their reflections on the LAI work which has already taken place in some boroughs, for example the Southwark transformation projects. The outcomes and learnings from the pilot will be useful for implementing better prescribing and monitoring of LAIs across SEL in primary care.

The Committee welcomed and noted the update on the LAI primary care project and thanked the presenter for their ongoing work in this area. Committee members agreed by consensus that an update on the project in 6 months would be useful.

ACTION: Update on long-acting antipsychotic injections (LAI) primary care project to be presented to the Committee in 6 months

6. Implementation of recommendations from NICE and London Diabetes Clinical Network on the use of continuous glucose monitoring (CGM) in adults with Type 1 Diabetes

The authors were in attendance alongside representation from the London Diabetes Clinical Network and the SEL ICB Long Term Conditions Commissioning team. The National Institute for Health and Care Excellence (NICE) updated their guidance on glucose monitoring and provided recommendations on the use of Flash Glucose Sensor and Continuous Glucose Monitoring (CGM) devices for the management of Type 1 diabetes (T1DM), Type 2 diabetes (T2DM) and children and young people (CYP) with diabetes. To support implementation, the London Diabetes Network and London Procurement Partnership have developed regional guidance for CGM in adults with T1DM. Members noted that development of London wide guidance for T2DM and CYP with diabetes is in progress at a London level.

Committee members were asked to note that SEL guidance for CGM in T1DM also includes CGM devices supplied via the hospital supply chain. These devices do not fall under the IMOC's usual remit and therefore the approval of the guidance from this perspective is outside the remit of the Committee. Committee members were advised that there has been assurance that the guidance has been reviewed and approved through the IMOC expert diabetes subgroup, which include local specialists and the London wide diabetes network. A view from Committee members was requested regarding any objections to the Committee operating outside its usual remit. Members agreed by consensus that it would be acceptable on this occasion for the Committee to consider the SEL CGM in adult T1DM guidance as a whole in the interest of maintaining a consistent approach to this work.

The pan-London guidance for adults with T1DM has been adapted for SEL and is being presented for approval as new guidance. Additionally, the existing pathway for flash glucose monitoring (which covers the previous NHS England Guidance) has also been updated to remove reference to the adult T1DM cohort. The following existing resources have also been updated to further support local implementation:

- Community pharmacy CGM in T1DM information sheet
- Primary care CGM in T1DM information sheet
- CGM request to primary care template letters

Alongside the local CGM in T1DM guidance, updated existing flash glucose pathway and supporting resources, Committee members were requested to approve the formulary inclusion of locally reviewed CGM devices available for prescribing on FP10 with a Green "red, amber, green, grey" (RAGG) rating for use in adults with T1DM.

Committee members were also requested to consider the recategorisation of Freestyle Libre™ Sensors from Amber 3 (*specialist initiation under shared care via a transfer of care document*) to Green for adult T1DM patients only. It was clarified that Freestyle Libre™ will remain as Amber 3 for patients with T2DM and CYP with diabetes previously approved until pan-London guidance for these cohorts is developed.

The Committee noted the costings for implementing CGM and flash glucose monitoring in adults with T1DM. In line with the Terms of Reference for the IMOC, as the cost impact exceeded the financial threshold, this was escalated to the Planning and Finance Committee in early March and has been noted and approved by the Planning and Finance Committee.

GP members raised comments regarding the proposed Green categorisation for CGM and flash glucose monitoring in people with T1DM. Views were shared regarding the risk of a green categorisation increasing the pressure on primary care clinicians to prescribe CGM and flash glucose monitoring without the clinical knowledge and expertise to do so. An Amber 1 categorisation (*initiation in primary care on advice of a specialist*) would be preferable.

The presenters clarified that primary care clinicians will not be obliged to initiate under the Green categorisation, primary care clinicians should only initiate CGM or flash glucose monitoring if they have the skill, knowledge and competency to and can still refer patients to specialist teams for initiation. The presenters also shared that SEL has had one of the best deliveries of technology in T1DM in regard to Freestyle Libre™ and CGM, however there has been a barrier to equitable access to these devices across SEL which has also influenced the proposed Green categorisation.

GP members fed back that an Amber 1 categorisation provides additional clarification that CGM and flash glucose monitoring should be initiated on the advice of a specialist and CGM. Under the amber 1 categorisation, CGM and flash glucose monitoring can still be initiated in primary care if the definition of a "specialist" includes primary care clinicians/teams with a specialist interest in diabetes or with the knowledge, skills and expertise to initiate CGM or flash glucose monitoring.

Committee members agreed the following by consensus, approval of:

- New CGM guidance for adults living with T1DM *(pending updates in line with the discussion)*
- Updated existing flash glucose pathway
- Community pharmacy CGM in T1DM information sheet
- Primary care CGM in T1DM information sheet
- CGM request to primary care template letters
- Formulary inclusion of locally reviewed CGM devices available for prescribing on FP10 as Amber 1
- Recategorisation of Freestyle Libre™ from Amber 3 to Amber 1 in adults with T1DM
- Freestyle Libre™ will remain as Amber 3 for the cohorts of people in the existing flash glucose guidance covering adults with T2DM and CYP with diabetes

Committee members also agreed by consensus the review of the CGM FP10 device Amber 1 categorisation in 1 year to enable expertise, knowledge, and skills to be developed in primary care through education and training. This will also enable the specialist teams to review if the inequalities to access of CGM and flash glucose monitoring in T1DM across SEL has improved.

ACTION: CGM guidance for adults living with T1DM to be updated in line with discussion and to be returned to the Committee for approval
ACTION: SEL JMF to be updated with the inclusion of Dexcom One™ sensors, Dexcom One™ transmitters and GlucoRx Aidex™ as Amber 1 for use in adults with T1DM and recategorisation of Freestyle Libre™ in adults with T1DM as Amber 1

7. Information sheet for primary care on the use of orodispersible budesonide (Jorveza™) in eosinophilic oesophagitis and draft formulary recommendation 141 - Jorveza™ in eosinophilic oesophagitis

The author was in attendance to present this item which has been developed following the formulary submission considered in October 2022 for the use of orodispersible budesonide (Jorveza™) as Amber 2 (*specialist initiation*) for the maintenance treatment for eosinophilic oesophagitis (EoE). The presenter clarified an update to the information sheet is required in relation to the dosing information for maintenance treatment with Jorveza™. The information sheet currently recommends Jorveza™ 0.5mg twice a day for maintenance treatment however some patients may require escalation of their maintenance treatment dose to 1mg twice a day.

A comment was raised in relation to the use of Jorveza™ 1mg twice a day as maintenance treatment and what proportion of patients are likely to require the higher maintenance treatment and whether this will affect the estimated costings associated with the maintenance treatment for Jorveza™ in this setting. The author was unable to provide clarification within the meeting, however post meeting, the presenter clarified that Jorveza™ 1mg BD will be used in approximately 10% of patients who require maintenance treatment and there is no cost implication of using 0.5mg or 1mg BD as there is no price difference between both formulations at this dose.

The drafted formulary recommendation for the use of Jorveza™ in this setting was presented; minor comments from the Triage panel were shared which included clarification that maintenance treatment may be initiated after the induction course has been started as opposed to maintenance treatment being initiated when relapse occurs.

Committee members approved the information sheet for primary care on the use of orodispersible budesonide (Jorveza™) in eosinophilic oesophagitis and approved formulary inclusion of Jorveza™ as

Amber 2 in this setting by consensus. The formulary recommendation was also approved by consensus pending the amendments discussed.

ACTION: Information sheet and formulary recommendation to be updated in line with discussion and progressed for Chair's ratification

8. Formulary inclusion of morphine sulphate orodispersible tablets (Actimorph™) for use in adults

The Formulary Pharmacist presented this item alongside a specialist head and neck cancer pharmacist who was in attendance. This formulary request was originally presented at the October 2022 IMOC meeting, where it was detailed that the plan is for a SEL Trust to undertake a switch to Actimorph™ as the first line brand of choice for immediate release morphine to improve governance, safety and cost effectiveness. Across the other SEL Trusts, Actimorph™ will be used in particular patient groups who may benefit from the Actimorph™ formulation for example in palliative care and for head/neck cancer patients.

At the October 2022 meeting safety concerns regarding the impact of the switch to Actimorph™ on primary care were shared by Committee members. These concerns have been discussed via the SEL ICS medicines safety network (SEL MSN) and the network have recommended the development of communication to be shared with primary care prior to the launch of the switch to Actimorph™. The Actimorph™ communication for primary care has been drafted and included within the agenda pack for information only. The proposed switch to Actimorph™ has also been discussed with the controlled drugs accountable officer (CDAO) for London, who is supportive and would be interested in any learning and outcomes from the switch in SEL if approved.

A comment was raised in regard to whether the majority of Actimorph™ prescribing will remain within secondary care. The presenter clarified Actimorph™ prescribing will remain within secondary care for majority of patients. Longer term use of Actimorph™ may also be required for palliative care and for head/neck cancer patients. Comments were also raised in relation to the off-label use of Actimorph™ as a mouthwash for the management of oral mucositis pain in head and neck cancer patients. The presenter clarified that use of Actimorph™ in this patient cohort will be for a small proportion of patients with intractable oral pain who are not well managed with Oramorph™ or co-codamol. The prescribing of Actimorph™ in this patient cohort will remain under the specialist team and categorised as Red (*hospital only*). The RAGG category for use in the licensed indication (severe pain which can be adequately managed only with opioids) will be Green.

Committee members approved by consensus the formulary inclusion of morphine sulphate orodispersible tablets (Actimorph™) as green for use in adults in its licensed indication and as Red for off-label use as a mouthwash in adults for the management of oral mucositis pain in head and neck cancer patients.

ACTION: Morphine sulphate orodispersible tablets as green for use in adults in the licensed indication and as Red for the management of oral mucositis pain in head and neck cancer adult patients to be added to the SEL JMF

9. Adaflex™ (melatonin) for use in insomnia in children and adolescents aged 6-17 years with attention deficit hyperactivity disorder (ADHD) where sleep hygiene measures have been insufficient

This formulary submission originates from SLaM and is supported by Oxleas and GSTT Evelina Children's hospital. The application requests the use of Adaflex™ (immediate release melatonin) first line for the management of insomnia in children and adolescents aged 6-17 years with attention deficit hyperactivity disorder (ADHD) where sleep hygiene measures have been insufficient.

- Ø **Evidence review**

The Formulary Pharmacist presented an overview of the efficacy evidence for the use of Adaflex™ in this setting, the detailed evidence review was provided within the meeting agenda pack. The information presented also included the estimated resource impact for Adaflex™ (immediate release melatonin) in this setting. The resource impact of the submission is within the financial threshold that the Committee is authorised to approve.

- **Applicant's presentation**

One of the applicants were in attendance to present the submission and field any questions. The applicant's DoI was noted. The applicant clarified that the formulary submission is for the use of Adaflex™ first line in line with its licensed indication. Adaflex™ would be a replacement for Circadin™ tablets, or other melatonin formulations which are currently in use within this patient cohort. Continued prescribing in primary care is desired after one month of stabilisation.

A comment was raised in regard to using Adaflex™ in line with the recommendation from the British Association for Psychopharmacology, where the use of melatonin to advance sleep onset to normal values in children with ADHD should be in children who are not on stimulant medication. The applicant clarified this would need to be raised with the main applicant. Post meeting via email, the main applicant clarified that Adaflex™ was designed to cover a licence for children with ADHD (and without Autism) who otherwise would have melatonin off licence. In the applicants' view, limiting Adaflex™ to children not on stimulants would not be helpful, given many patients have sleep onset difficulties before taking stimulants and the use of Adaflex™ would be used to resolve the existing sleep onset difficulties. In addition to this, using Adaflex™ in this manner would exclude most patients given that many would be (as per the evidence for effectiveness) on stimulant therapy.

Another comment was raised in regard to the request to transfer the prescribing of Adaflex™ to primary care after one month of stabilisation. In line with the current melatonin preparations approved for use in SEL, Committee members agreed that any use of Adaflex™ would need to be under the same arrangements which is transfer to primary care after 2 months of stabilisation under the Amber 3 (shared care) categorisation. Committee members also agreed, if Adaflex™ is approved for use in this setting, the paediatric melatonin shared care guideline and prescribing pathway will require a review and update before any final decision on formulary inclusion is made.

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

Committee members discussed the application and members acknowledged that Adaflex™ is suitable as a first line treatment option for use in insomnia in children and adolescents aged 6 -17 years with ADHD where sleep hygiene measures have been insufficient in line with the product licence. Whilst minded to recommend approval as Amber 3 (shared care), a final decision can only be made once the paediatric melatonin shared care guideline and prescribing pathway have been updated. Until this has been completed, Adaflex™ will remain non-formulary in SEL.

ACTION: Paediatric melatonin shared care guideline and prescribing pathway to be updated with the inclusion of Adaflex™ and presented at a future meeting
ACTION: Formulary recommendation to be drafted and presented at a future meeting once the shared care guidance and prescribing pathway have been updated

10. Treatment pathway for various agents for the treatment of co-morbid insomnia in adult patients following formulary application in October 2021 (off-label use)

The author was in attendance to present this item. This pathway has been developed following initial discussions in October 2021, where formulary applications for a number of agents in this setting were considered. An initial draft pathway was presented at the October 2021 and August 2022 meeting and this has been refined in line with discussions and comments following a SEL wide consultation.

A comment was raised in relation to further clarifying within the pathway which treatment options are Amber 2 as only the treatment options categorised as Red are clear.

Committee members approved the treatment pathway for various agents for the treatment of co-morbid insomnia in adult patients by consensus pending the requested amendment as per the discussion.

ACTION: Pathway to be updated in line with the discussion and progressed for Chair's ratification
ACTION: Formulary recommendation to be drafted and presented at next meeting

11. Formulary request for the use of aripiprazole in paediatrics in the following off label indications:

- **Irritability associated with Autistic Spectrum Disorder (ASD)**
- **Treatment of Tourette's disorder**

The Paediatric Formulary Pharmacist was in attendance to present this item, which is a request to formalise the current use of aripiprazole by SLaM, Oxleas and the Evelina Children's hospital in this setting. The formulary request is in line with the licensed use of aripiprazole in the United States (US) for irritability associated with Autistic Spectrum Disorder (ASD) and Tourette's disorder in paediatrics.

The presenter outlined that NICE guidance for ASD recommends treatment with the use of antipsychotics, however, does not specifically mention aripiprazole as the antipsychotic of choice. Aripiprazole is considered the antipsychotic of choice as it is better tolerated and has fewer side effects in comparison to other antipsychotic's such as weight gain.

The Committee was requested to consider the formulary request for the use of aripiprazole in this setting as Amber 2 (*specialist initiation followed by transfer to primary care*).

A comment was raised recommending the development of a factsheet to support GPs when transfer of prescribing and monitoring occurs which includes information around stock shortages and adverse effect management. Additional comments were raised by Committee members requesting the review of local data on the adverse effects of aripiprazole when used in this setting as aripiprazole in this patient cohort is off-label. The adverse effect profile of aripiprazole, especially the metabolic effects, is quite extensive in adults and Committee members agreed It would be useful to review real world data relating to use of aripiprazole in paediatrics in this setting.

Committee members agreed by consensus that a decision would be deferred until additional supporting data are provided as discussed. Members requested the submission of the additional supporting data to be presented to the Committee at a future IMOC meeting for review.

ACTION: Additional supporting data in line with the discussion for the use of aripiprazole in this setting to be presented at a future IMOC meeting

12. Standing items/Items for information only

- Formulary Submissions tracker

Noted

- NICE Technology Appraisal (TA) Guidance Summary – ICS attributed medicines & NHSE/I
- The summary was noted and Red, Amber, Green, Grey (RAGG) categories were agreed by consensus. Committee members noted that a RAGG categorisation for semaglutide (Wegovy™) for managing overweight and obesity (in adults) is to be confirmed as there are ongoing discussions regarding implementation and Wegovy™ has not yet been launched in the UK.

13. Any Other Business:
No items raised.

IMOC dates for next 3 months

Date	Time	Venue
20th April 2023	2:00pm – 4:30pm	MS Teams
18th May 2023	2:00pm – 4:30pm	MS Teams
15th June 2023	2:00pm – 4:30pm	Hybrid – MS Teams/in person