South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
17 August 2023 (Meeting held via MS Teams)
Final Minutes

1. **Welcome, introductions and apologies**
   The Chair welcomed attendees to the meeting. Apologies 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 minor typographical corrections. Members were provided with an update on progress against actions due for this month, these were noted, and items closed were agreed.

4. **i. Updated guidance on the pharmacological management of heart failure**
   ii. Recategorisation request for sacubitril/valsartan from Amber 3 to Amber 2 for the management of heart failure:
   - **Sacubitril/valsartan patient pathway**
   - **Sacubitril/valsartan FAQ**

   The authors were in attendance to present this item which has been completed through the CVD sub-group.

   (i) Updated guidance on the pharmacological management of heart failure

   Updates to the overarching guidance include a section on the management of heart failure (HF) with preserved (HFpEF) and mildly reduced (HFmrEF) ejection fraction, inclusion of sodium glucose cotransporter-2 inhibitors (SGLT2i) for the management of HF with reduced ejection fraction (HFrEF), HFpEF and HFmrEF following publication of National Institute of Health and Care Excellence (NICE) guidance and addition of overprescribing review considerations.

   (ii) Recategorisation request for sacubitril/valsartan from Amber 3 to Amber 2 for the management of heart failure

   Alongside the approval of the updated HF guidance, Committee members were also requested to consider the recategorisation request for sacubitril/valsartan from Amber 3 to Amber 2 supported by the development of a sacubitril/valsartan patient pathway guidance and frequently asked questions (FAQ). The proposal is that under the Amber 2 category, sacubitril/valsartan will be initiated by the specialist HF team with 1 month supply followed by continued prescribing in primary care. The HF team will still conduct any required dose titrations and monitoring.

   With respect to the resource impact of the recategorisation, information provided to the Committee states that spend is already occurring in the local healthcare system and current prescribing is below NICE predictions/resource template for the NICE TA. As this is a recategorisation request, it is not expected that there will be additional costs compared to baseline.

   Committee members were requested to note comments shared prior to the meeting with the author which the author has agreed to implement. This includes removing reference to European guidance, which does not align to current guidance from NICE. Additional comments have also been shared with the author prior to the meeting from leads of the diabetes sub-group, which are to be actioned.

   Whilst borough GP clinical leads present at the meeting supported the move to Amber 2, they expressed concerns regarding the one month transfer of prescribing with the Amber 2 recategorisation. Members felt that under a definition of Amber 2, GPs would take over once the patient is on a maintenance dose and therefore a 1 month transfer period would not be sufficient for all patients. The presenters clarified that the 1 month transfer of prescribing was selected to enable a consistent approach for all patients, as some patients will be on a maintenance dose at 4 weeks and for patients who have yet to achieve maintenance

dose at 1 month will be monitored by the HF team with a clear management plan. The GP leads fed back that delays in clinic letters reaching the GP practices would impact on continual supply in primary care if only one month's supply is provided to the patient. At 1 month, patients may still be undergoing titration and monitoring, and it will be more appropriate and safer to transfer prescribing to primary care at the point of maintenance treatment, as is the norm in situations where specialist medicines are initiated and titrated.

Committee members indicated they were happy to approve the updated pharmacological management of heart failure guidance, recategorisation of sacubitril/valsartan from Amber 3 (shared care) to Amber 2 (specialist initiation) and associated sacubitril/valsartan patient pathway and FAQ by consensus pending updates in line with the discussion. However there was no consensus agreement reached on the 1 month transfer of prescribing associated with the sacubitril/valsartan recategorisation. Due to the concerns with reducing the transfer time to 1 month and the number of updates requested to the documents, it was agreed that the documents would either need to return to Committee or be taken via the Triage Panel for ratification once updated.

Post meeting note: *As there was no clear consensus reached on the 1 month transfer of prescribing for sacubitril/valsartan under Amber 2 arrangements, the updated documents will need to be re-presented at the September IMOC meeting for final ratification.*

ACTION: Documents to be updated by authors in line with feedback
ACTION: Updated pharmacological management of heart failure guidance and recategorisation request for sacubitril/valsartan from Amber 3 to Amber 2 and associated patient pathway and FAQ to be presented at a future IMOC meeting for approval

5. Guideline for the use of dapagliflozin for treating patients with chronic heart failure with preserved (HFpEF) or mildly reduced ejection (HFmrEF) and cost modelling for SEL

The authors were in attendance for this item which has been developed to support implementation of NICE Technology Appraisal (TA) 902 for use of dapagliflozin for the management of HFpEF and HFmrEF. In line with the existing categorisation for dapagliflozin in HFrEF, Committee members were requested to consider a RAGG category of Amber 1 *(primary care initiation on advice of a specialist)* for dapagliflozin in this setting.

The Committee noted the estimated cost impact over time for dapagliflozin in this setting, which exceeds the delegated authority for the SEL IMOC membership to approve. In line with the Committee Terms of Reference, as the cost impact exceeds the agreed financial threshold, this will be escalated to the ICB Executive Committee in September. 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. Approval of the guideline via the Committee at this IMOC meeting will be on a clinical basis only.

Additional comments have been shared prior to the meeting with the author from leads of the diabetes sub-group which are to be actioned. A comment was raised in regard to who will be responsible for conducting the baseline monitoring. The presenter confirmed this will be the responsibility of the specialist initiating team.

Committee members clinically approved the guideline for the use of dapagliflozin for treating patients with HFpEF or HFmrEF by consensus pending updates to the guideline in line with the discussion and an Amber 1 category for the use of dapagliflozin in this setting. The cost modelling will be shared with the Executive Committee for information.

ACTION: Guideline for the use of dapagliflozin for treating patients with HFpEF or HFmrEF to be updated and progressed for ratification via Chair's action
ACTION: Dapagliflozin for treating patients with HFpEF or HFmrEF to be added to the SEL JMF as Amber 1 once the guideline is ratified
ACTION: Estimated cost impact to be escalated to the Executive Committee for information

6. Inclisiran FAQs for primary care practitioners

The author was in attendance to present this item which has been developed to support primary care with the prescribing and administration of inclisiran. The FAQ aims to answer the most common questions in relation to inclisiran and to support learning for primary care healthcare professionals.

A comment was raised in relation to including a question on the arrangements in SEL for prescribing inclisiran within the FAQ as this information is not currently easy to locate within the document. An additional comment was raised in relation to any local safety related patient issues with the use of inclisiran, the author clarified all patients who have been initiated on inclisiran locally have tolerated treatment well.

Committee members approved the inclisiran FAQs for primary care practitioners by consensus pending updates in line with the discussion.

ACTION: Inclisiran FAQs for primary care practitioners to be updated and progressed for ratification via Chair's action.

7. Clinical Effectiveness South East London (CESEL) asthma for adults and children & young people guide - medicines section

The authors were in attendance to present this item which has been developed in line with the Pan-London asthma treatment pathway and Pan-London respiratory formulary. The adult and children and young people (CYP) asthma guides have been developed collaboratively across SEL with input from both primary and secondary care colleagues and the respiratory sub-group of the IMOC. The Committee is being requested to approve the medicines sections of the guides.

The adult asthma CESEL guide will update and replace the existing IMOC integrated adult asthma treatment pathway whereas the CYP asthma CESEL guide is new local guidance. The implementation of the guides will be supported by educational webinars and in person practice visits to support quality improvement in the management of asthma in SEL.

The Formulary Pharmacist presented an overview of the efficacy evidence for the use of "As Needed Anti-Inflammatory Reliever (AIR)" therapy with inhaled corticosteroid (ICS)-formoterol (budesonide/formoterol or beclomethasone/formoterol) as the preferred option for step 1 asthma management and long acting muscarinic agonists (LAMA) as an option prior to escalation to high dose ICS.

A detailed evidence review was provided within the meeting agenda pack. The information presented also included the estimated resource impact for AIR therapy and LAMA as an option prior to escalation to high dose ICS. The resource impact of the submission is within the financial threshold that the Committee is authorised to approve.

Committee members were also requested to consider the formulary inclusion of various inhalers for adults and CYP in line with the Pan-London respiratory formulary and the removal of inhaler devices which are on the previous local guidance and medicines formulary but not in the revised guidance incorporated in the CESEL guide. The resource impact of the additional inhalers, which are in line with the Pan-London respiratory formulary, is within the financial threshold that the Committee is authorised to approve.

A comment was raised in relation to highlighting the SABA free pathway (AIR therapy) as the preferred option in relation to the SABA pathway within the guide, as in line with the evidence it provides better outcomes for the management of asthma. Members queried how the outcomes from this new guidance would be monitored. It was confirmed that this will be progressed through the respiratory sub-group working with the business intelligence team.

The Committee approved the following by consensus:

- The medicines sections of the CESEL guides for adult asthma and children & young people - pending updates to the guide in line with the discussion followed by approval via IMOC Chair's ratification

- AIR therapy as initial asthma treatment (ICS-formoterol prn) in children aged 12 and over and adults, noting that beclomethasone/formoterol (Fostair™) is off-label use.
- LAMA as an option prior to escalation to high dose steroids
- New adult inhaler formulary inclusions, in line with the pan-London formulary
- New and historic paediatric formulary inclusions
- Removal of selected inhaler devices not within the CESEL guide

ACTION: Authors to update the CESEL adult and CYP asthma guide in line with discussions and progress for IMOC Chair's ratification
ACTION: Addition of approved adult inhalers and paediatric inhalers to the SEL JMF
ACTION: Addition of approved paediatric inhalers to paediatric formulary

8. Genomic Medicine and Medicines Optimisation

A member of the NHS South East Genomic Medicine Service Alliance was in attendance to present an overview of the regional genomic medicine services under the Genomic Medicine Service Alliances (GMSA) and how these link into medicines optimisation. There are seven GMS Alliances in England which include seven NHS Genomics Laboratory Hubs which perform genomic testing, analysis and interpretation with multidisciplinary teams. It was highlighted that there are currently three pharmacogenomic tests listed in the Genomic Test Directories in relation to medicines and NICE will be reviewing some of the pharmacogenomic tests through their Diagnostic Assessment Programme. Engagement with RMOC as well as local IMOCs is underway, and a collaborative network is open to members to receive updates on developments.

Committee members noted the presentation and thanked the presenter for sharing an overview of genomic medicine and medicines optimisation. Further updates will be arranged in the future.

9. i. Formulary inclusion of tacrolimus 0.1% and 0.03% ointment and pimecrolimus 1% cream for dermatological conditions where there is a need to limit the adverse effects from topical corticosteroids (off-label) as Amber 1

ii. Recategorisation request for tacrolimus 0.1% and 0.03% ointment and pimecrolimus 1% cream from Amber 2 to Green for the management of eczema and psoriasis (licensed and off-label indications)

The applicants, both members of the IMOC dermatology sub-group and leads for the primary care dermatology guidance, were in attendance to present these items. The requests have been reviewed and recommended via the dermatology sub-group. The off-label use of the topical calcineurin inhibitors (TCIs) tacrolimus and pimecrolimus in adults and paediatrics to limit adverse effects from topical corticosteroids (TCS) will be in dermatological conditions where typically potent or super potent topical steroids could potentially be used for long durations. The Amber 1 categorisation will enable GPs to prescribe TCIs following advice and guidance, allowing patients to receive the treatment earlier in comparison to waiting for treatment via the community dermatology clinics, which currently have extended waiting times.

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

Committee members were also requested to consider the recategorisation of tacrolimus and pimecrolimus from Amber 2 (*specialist initiation*) to Green (*primary care or specialist initiation*) for the management of eczema and psoriasis (licensed and off-label indications). This recategorisation would also support patients to receive treatment earlier via their GPs.

Committee members fed back that a recategorisation of Amber 1 may be more suitable for tacrolimus and pimecrolimus for the management of eczema and psoriasis as many GPs are not comfortable with prescribing TCIs in this setting and these medicines are usually initiated by specialists. A comment was also raised in relation to the safety concerns associated with TCIs and how patients will be reviewed. The

applicant clarified GPs will be responsible for reviewing treatment with the aim of stepping down treatment once a patient is stable and step treatment back up when required.

Committee members agreed by consensus the formulary inclusion of tacrolimus 0.1% and 0.03% ointment and pimecrolimus 1% cream off-label in adults and paediatrics for dermatological conditions where there is a need to limit the adverse effects from topical corticosteroids as Amber 1. Members also agreed by consensus that a category of Green would not be supported for the use of tacrolimus 0.1% and 0.03% ointment and pimecrolimus 1% cream in the management of eczema and psoriasis (licensed and off-label indications). Instead, Committee members agreed by consensus a recategorisation from Amber 2 to Amber 1.

ACTION: Primary care dermatology guidelines to be updated with the inclusion of topical tacrolimus and pimecrolimus for dermatological conditions where there is a need to limit the adverse effects from topical corticosteroids and recategorisation to Amber 1 for the management of eczema and psoriasis

ACTION: Topical tacrolimus and pimecrolimus for dermatological conditions where there is a need to limit the adverse effects from topical corticosteroids and recategorisation to Amber 1 for the management of eczema and psoriasis to be added to the SEL JMF once the guideline is updated and approved

10. Paediatric formulary inclusion of ivabradine for management of:

- **Heart Failure (as Amber 2)**
- **Tachycardia associated with postural orthostatic hypotension (POTS), tachyarrhythmias including atrial ectopic tachycardias (AET) and junctional ectopic tachycardias (JET) (as Amber 3)**

One of the applicants and specialist paediatric pharmacist were in attendance to present this item which formalises the existing use of ivabradine in this setting. The use of ivabradine in patients below 18 years is unlicensed, however in a multicentre study, it was shown that ivabradine is safe in paediatric patients with HF. Ivabradine is approved for use in adults locally for the treatment of HF (Amber 2) and in POTS (Amber 3). The use of ivabradine in AET and JET is not covered in the adult local formulary, which is likely due to JET and AET occurring in children as opposed to adults.

From local experience, ivabradine appears to be a safe and well-tolerated medication in this patient cohort. Patients are closely monitored for bradycardia and QTc prolongation. When witnessed, bradycardia and QTc prolongation have self-resolved on cessation of therapy. All patients will remain under the regular review and monitoring of the specialist team.

A summary of the evidence was provided within the meeting agenda pack. The resource impact for the use of ivabradine in this setting is within the financial threshold that the Committee is authorised to approve.

A comment was raised in relation to the treatment options which are usually trialled before ivabradine in this patient cohort. The presenter clarified for POTS and the tachyarrhythmia conditions, lifestyle changes are often recommended to lessen the effects of symptoms. For the tachyarrhythmia conditions, propranolol and fludrocortisone is also trialled prior to ivabradine. A comment was also raised in regard to how often patients will be monitored by the specialist team, as it is a small cohort of patients, could prescribing be conducted by the specialist team if being seen regularly? The presenter clarified that patients are generally reviewed by the specialist team every 6 months and once patients become stable this would be an annual review which would make prescribing via the Trust difficult. In response to another query, the applicant clarified that the majority of symptoms experienced by JET patients is a post operative phenomenon and tends to settle after a week to 10 days. In view of this, the applicant in attendance accepted that a transfer of prescribing to primary care would not be essential for this cohort.

A consensus view from Committee members was not reached in the time available at the meeting. Further views from GP committee members would be useful. It was recommended that a revised,

streamlined proposal including the place in therapy in the pathways for ivabradine is presented back to the Committee for further review and discussion.

11. Outcome data for the use of apixaban for thromboprophylaxis in renal haemodialysis patients

The formulary pharmacist presented this item following the formulary application approval in June 2022 which requested the presentation of outcome and safety data for the use of apixaban in this setting in 12 months. At GSTT over the last 2.5 years apixaban (2.5mg twice daily) has been used in 33 patients in this setting. There were no major bleeding episodes and a few incidents of clinically relevant non-major bleeding, however apixaban continued in all cases. A few patients also experienced stroke, one of which may have been due to AF. At KCH, one patient has been started on apixaban in this setting over the last 12 months and remains on treatment with no complications. No patients have been initiated on apixaban in this setting at LGT as there is no haemodialysis service.

The original application estimated 50 patients per year across SEL would be eligible for treatment, however the outcome data demonstrates the use of apixaban in this setting is lower than expected. Upon review of the outcome data, the applicants confirmed there is no current desire to recategorise apixaban in this setting from Red to an Amber rating as originally discussed in June 2022. The RAGG status is therefore to remain as Red.

Committee members noted the outcome data and the continued red RAGG category.

ACTION: Formulary recommendation 133 to be updated in line with the presented outcome data

12. Standing items

- Formulary submissions tracker

Noted.

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

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

- Regional Medicines Optimisation Committee (RMOC) update – August 2023:

The Committee noted an update from the August RMOC meeting, including updates on planned new arrangements for gender dysphoria clinics, regional Academic Health Science Networks (AHSN) projects to improve the management of patients prescribed high dose opioids and the genomic medicines service.

13. Any Other Business

Nil items raised.

IMOC dates for next 3 months

Date	Time	Venue
21st September 2023	2:00pm – 4:30pm	MS Teams
19th October 2023	2:00pm – 4:30pm	Hybrid – MS Teams/in person
16th November 2023	2:00pm – 4:30pm	Hybrid – MS Teams/in person