South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
20th February 2025 (Online via MS Teams)
Final Minutes

1. **Welcome, introductions and apologies**
   The Chair welcomed attendees to the meeting. Apologies were noted 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. No conflicts were raised.

3. **Detailed action notes of the last meeting, minutes, and action log:**
   The minutes and detailed action 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. **Updated viral warts pathway and associated formulary recommendation**

   The authors were in attendance to present this item on behalf of the dermatology sub-group. The viral warts pathway which forms part of the primary care dermatology guidelines has been updated to include Actikerall® (10% salicylic acid and fluorouracil 0.5% in a solution formulation) following the September 2024 IMOC meeting where Actikerall® was approved as Amber 1 in adults and children for the management of recalcitrant, very symptomatic warts impacting on the activities of daily living. The approval was pending the pathway update.

   Committee Members discussed the updated pathway, and a query was raised in relation to the use of Actikerall® in children and whether there is there an age limit for its use. The presenters confirmed it is unlikely for children under the age of 5 to be diagnosed with viral warts and the use of Actikerall® would be in children aged 5 years and older. The pathway and formulary recommendation will be updated to reflect this. In response to a query about the inclusion of cryotherapy freeze time recommendations within the pathway despite cryotherapy not usually being available on the NHS, the presenter agreed to update this section to include information which supports clinician and patient discussions regarding cryotherapy and why it is not usually available on the NHS. The presenters also agreed to clarify within the pathway that the use of Actikerall® is specifically recommended in patients whose activities of daily living is affected by their untreated viral warts

   Formulary recommendation:

   - **New - Actikerall™ (salicylic acid 10% and fluorouracil 0.5%) solution for the management of recalcitrant warts (off-label) in adults and children where previous treatments have failed or are inappropriate**

   This formulary recommendation has been drafted following the approval of Actikerall® at the September 2024 IMOC meeting. In line with the discussions earlier in the meeting, the agreed age group for the use of Actikerall® in children will be added to the formulary recommendation. Committee members approved the formulary recommendation by consensus.

   Committee members also approved by consensus the updated viral warts pathway pending amendments in line with the discussions.

   ACTION: Author to amend pathway in line with meeting discussions and share with the IMOC team to progress for IMOC Chair's ratification

5. **Keloid and hypertrophic scar treatment pathway and associated formulary recommendation**

   The authors remained to present this item on behalf of the dermatology sub-group. The keloid and hypertrophic scar treatment pathway is a new pathway, developed and consulted on locally. The

pathway was developed following the September 2024 IMOC meeting where betamethasone 2.25mg medicated plasters (Betesil®) and fludroxycortide 4 microgram/cm^2 tape were approved as Amber 1 for the management of keloid and hypertrophic scars in adults. The keloid and hypertrophic scar treatment pathway will form part of the primary care dermatology guidelines.

In line with the proposed pathway, the initial treatment of keloids or hypertrophic scars is with silicone dressings or gel (for scalp use) which is available over the counter (OTC). If the keloids or hypertrophic scars become symptomatic, advice and guidance should be sought for the recommendation to prescribe Betesil® or fludroxycortide 4 microgram/cm^2 tape for 12 weeks, with a preference for Betesil® which is currently more cost effective than fludroxycortide 4 microgram/cm^2 tape. The use of Betesil® for the duration of 12 weeks for the management of keloids or hypertrophic scars is off-label (licensed a maximum of 30 days). For patients who particularly experience difficulty sleeping due to their symptoms or symptoms are impacting their daily living activities, alternative treatment on the formulary is available with topical clobetasol propionate 0.05% cream for daily application under occlusion. If patients experience inadequate symptomatic relief after 12 weeks of treatment with Betesil® or fludroxycortide 4 microgram/cm^2 tape or topical clobetasol; patients should be referred to community dermatology services for intralesional triamcinolone injections.

Committee Members discussed the presented pathway; a comment was raised in relation to the use of intralesional triamcinolone (Adcortyl®) which is currently in the local formulary for the management of keloids and hypertrophic scars but uncategorised. In line with its place in therapy as per the pathway, Adcortyl® (licensed for this use) should be RAGG categorised as Red and reflected in the pathway, the presenter agreed to update the pathway to reflect this. A query was raised in relation to patients who do not experience symptomatic keloids or hypertrophic scars but also do not achieve the aesthetic outcome with silicone dressings, would these patients be considered for treatment with Betesil® or fludroxycortide 4 microgram/cm^2 tape. The presenter clarified this cohort of patients fall outside of the recommended use for Betesil® or fludroxycortide 4 microgram/cm^2 tape and they would need to be referred to the community dermatology clinic.

Formulary recommendation:

- **New - Betesil™ (betamethasone valerate) 2.25mg plasters and fludroxycortide 4 micrograms/cm^2 tape for the treatment of symptomatic hypertrophic or keloid scars in adults**

This formulary recommendation has been drafted following the approval of Betesil® or fludroxycortide 4 microgram/cm^2 tape at the September 2024 IMOC meeting. A comment was received via the virtual triage panel review in relation to clarifying that treatment for keloid scars or hypertrophic scars is with either Betesil® or fludroxycortide 4 microgram/cm^2 tape as opposed to both treatments.
Committee members approved the formulary recommendation by consensus pending this amendment.

Committee members also approved by consensus the keloid and hypertrophic scar treatment pathway pending amendments in line with the discussions.

ACTION: Author to amend pathway in line with meeting discussions and share with the IMOC team to progress for IMOC Chair's ratification

6. **SEL Acute Provider Collaborative (APC) Primary & Secondary care General Surgery Guidelines (IMOC is approving the medicines content only) and associated formulary request:**
    - **Request to recategorise diltiazem 2% cream from Red to Amber 1 for anal fissures (unlicensed)**

The authors were in attendance to present the item. The presenters outlined the work to develop these guidelines, and they cover the following set of common general surgery conditions seen in primary and secondary care: surgical same day emergency care, anorectal abscess and fistula, pilonidal abscess and sinus, rectal bleeding, anal fissure and haemorrhoids, right upper quadrant pain / gallstones pathway, gallbladder polyps and hernia.

The guidelines were circulated for consultation with the IMOC as well as a broader consultation including the Local Medical Committee (LMC). The anal fissure and haemorrhoids guideline contains medication related advice and the medicines content within the anal fissure and haemorrhoids guideline will result in the existing anal fissure IMOC guidance being retired as the content has moved into these broader APC guidelines.

Alongside the request to approve the medicines content of the APC primary and secondary care general surgery guidelines, there is a formulary request to recategorise diltiazem 2% cream in the adult joint medicines formulary (JMF) from a RAGG category of Red (hospital only) to Amber 1 (initiation in primary care upon specialist recommendation) for the management of anal fissure in adults. The place in therapy for diltiazem 2% cream as Amber 1 is intended to be the same as its current formulary recommendation.

The cost impact of recategorising diltiazem 2% cream as Amber 1 on the formulary is within the delegated financial threshold for the Committee and is already established as a healthcare system cost in secondary care. There are savings expected from reduced referrals to secondary care.

Committee Members discussed the presented guidelines and requested that clarity is provided within the anal fissure and haemorrhoid guideline in relation to diltiazem 2% cream highlighting that it is an unlicensed special and has an Amber 1 category. The presenters also confirmed that advice and guidance should be used by primary care to seek specialist advice for the initiation of diltiazem 2% cream and this will be made clearer in the guideline. A comment was raised regarding the current practice for patients requiring diltiazem 2% cream and the recategorisation of diltiazem 2% cream from Red to Amber 1. Currently most patients are referred to secondary care for diltiazem 2% cream so the recategorisation to Amber 1 may not be suitable. The presenter clarified that the aim of the guideline is to change this practice and enable patients to trial diltiazem 2% cream in primary care before requiring referral into secondary care.

Committee members approved by consensus the medicines content of the APC Primary & Secondary care General Surgery guidelines pending amendments in line with the meeting discussions and the recategorisation of diltiazem 2% cream from Red to Amber 1 for the management of anal fissure in adults.

ACTION: Author to amend guideline in line with meeting discussions and share with the IMOC team to progress for IMOC Chair's ratification
ACTION: Recategorisation of diltiazem 2% cream as Amber 1 to be added to the SEL JMF once the APC guideline is approved
ACTION: Diltiazem 2% cream formulary recommendation to be updated in line with recategorisation to Amber 1

7. Updated Clinical Effectiveness South East London (CESEL) Type 2 Diabetes Mellitus (T2DM) guide

The author was in attendance to present this item. The CESEL T2DM guide has been updated to amalgamate the six separate borough T2DM CESEL guides, there has been minimal updates to the medicines content of the guide. The main updates to the guide include:

- Health inequalities: inclusion of socio-economic factors and learning disabilities
- A new pregnancy and planning for pregnancy section
- Self-monitoring of glucose

The updated CESEL T2DM guide was consulted on locally and many comments were received in relation to the glycaemic control sections of the guide. However, as the updated NICE T2DM guideline is due in Summer 2025, the CESEL guide has not undergone any major updates and currently aligns to the SEL IMOC T2DM glycaemic control management pathway.

Committee members were informed endorsement of the updated CESEL T2DM guide for the diabetes sub-group is still underway.

Committee Members discussed the presented guide and minor comments were raised in relation to updated links within the guide for the SEL IMOC lipid management and the CESEL hypertension guide. A comment was also raised regarding the availability of data on how often the CESEL guides are accessed. The presented clarified that this data is not captured as the guides are available online via an open access webpage. This data would only be available if the guides were uploaded to a password protected webpage. However anecdotally, the CESEL guides are widely used, and surveys have been sent out to understand the use and purpose of the CESEL guides. Educational events have also been held to support the implementation of CESEL guides.

Committee members approved by consensus the medicines content of the CESEL Type 2 Diabetes Mellitus guide pending amendments in line with the discussions and pending endorsement by the diabetes sub-group of the IMOC.

ACTION: Author to amend guide in line with meeting discussions and confirm endorsement of the guide by the diabetes sub-group of the IMOC

8. **Review of the "Red, Amber, Green" (RAG) category ratings & associated formulary requests for epilepsy in adults and paediatrics**

The authors presented this item with support from the King's College Hospital Principal Pharmacist for Neurosciences. This is a request to standardise the local approach to the prescribing of anti-epileptic medicines in adults and paediatrics due to the varying RAG categories within the local formulary for anti-epileptics. This review also requests the removal of the transfer of care documentation for anti-epileptic medication categorised as Amber 3 (shared care) and in line with this a recategorisation to Amber 2 (specialist initiation and first prescription from secondary care) as the transfer of care documents are no longer utilised in practice.

The aim of this request is to standardise the RAG ratings and prescribing requirements for anti-epileptic medicines whilst improving patient experience and removing barriers to prescribing. To support the prescribing of anti-epileptic medicines in primary and secondary, the NICE guideline NG217 - Epilepsies in children, young people and adults will be signposted to within the anti-epileptic medicine monographs within the adult and paediatric formulary. This also forms part of the paediatric formulary RAG review.

The summary of changes table provided within the agenda pack summarises the current and proposed RAGG categories for the anti-epileptics included within the adult and paediatric formulary. The proposed change is for all anti-epileptics not currently RAG rated as Amber 2 to be recategorised as Amber 2 for both adults and paediatrics.

In all instances, the first prescription will come from secondary care. In line with this, there is a proposed change in relation to the supply of brivaracetam following initiation; brivaracetam which is categorised as Amber 2, is supplied by secondary care for the first six months following initiation. The request is to change this requirement to the first prescription being supplied by secondary care following initiation in line with the other anti-epileptics.

All anti-epileptic injection formulations will remain categorised as Red unless categorised as amber for palliative care.

Formulary request for brivaracetam preparations as Amber 2 for the adjunctive therapy of focal seizures with or without secondary generalisation in paediatrics (historical use)

As part of the paediatric formulary RAG review, this formulary request is for the inclusion of brivaracetam injection, solution and tablets as Amber 2 for the adjunctive therapy of focal seizures with or without secondary generalisation in paediatrics based on historical use. The use of brivaracetam in this patient cohort is in line with NICE guideline NG217 and dosing in line with the British National Formulary for Children.

The cost impact of including brivaracetam preparations in the paediatric formulary is within the delegated financial threshold for the Committee. However, it is thought the inclusion of brivaracetam to the paediatric formulary will not have an impact on prescribing cost as there is established use in practice, which this request aims to formalise.

Formulary request for stiripentol capsules and sachets as Amber 2 for adjunctive therapy of refractory generalized tonic-clonic seizures in adults with Dravet's syndrome (historical use)

This formulary request is for the inclusion of stiripentol capsules and sachets as Amber 2 for the adjunctive therapy of refractory generalized tonic-clonic seizures in adults with Dravet's syndrome and is based on historical use. Dravet's syndrome is a type of genetic epilepsy which does not respond very well to conventional anti-epileptics. Seizures usually start in childhood and patients usually need support and care throughout their life. Stiripentol is licensed for this indication in children under the age of 18, but the Summary of Product Characteristics (SPC) notes that for patients aged 18 years old and older, long-term data has not been collected in a sufficient number of adults to confirm maintenance of effect in this population. Treatment should be continued for as long as efficacy is observed.

There are many patients who are started on stiripentol as a child and then transition into adult services and continue stiripentol, and there are a small number of adult patients who may be initiated on stiripentol due to late diagnosis.

The cost impact of including stiripentol capsules and sachets in the adult formulary is within the delegated financial threshold for the Committee. It was noted that in the last 12 months, there have been FP10 prescriptions for stiripentol across adults and paediatrics, demonstrating there is established use of stiripentol in primary care.

A comment was raised in relation to whether the formulary request for stiripentol is specifically for patients who are initiated on treatment as an adult. The presenter clarified that the formulary request is for patients initiated on treatment as an adult as paediatric patients would transition to adult services and such use is not usually reflected on the formulary. Members requested the criteria for initiating stiripentol in adults should be included within the adult formulary. A comment was also raised in relation to whether stiripentol has a titration period and if it is the first prescription which is only supplied by secondary care. The presenter confirmed the first prescription will be supplied by secondary care which will be a one month supply and the titration plan will be provided within the clinic letter/individual management plan which is sent to the GP.

Committee members approved the following by consensus:

- Anti-epileptics not currently RAG rated as Amber 2 to be recategorised as Amber 2 for both adults and paediatrics
- The change in prescription supply from secondary care for brivaracetam following initiation from 6 months to the first prescription as Amber 2
- Formulary inclusion of brivaracetam injection, solution and tablets as Amber 2 for the adjunctive therapy of focal seizures with or without secondary generalisation in paediatrics
- Formulary inclusion of stiripentol capsules and sachets as Amber 2 for the adjunctive therapy of refractory generalized tonic-clonic seizures in adults with Dravet's syndrome

ACTION: Paediatric formulary to be updated with the approved RAG category changes for anti-epileptics in paediatrics and addition of NICE NG217 to anti-epileptic monographs
ACTION: Adult formulary to updated with approved RAG category changes for anti-epileptics in adults and addition of NICE NG217 to anti-epileptic monographs
ACTION: Brivaracetam injection, solution and tablets to be added to the paediatric formulary as Amber 2
ACTION: Stiripentol capsules and sachets to be added to the adult formulary as Amber 2 with criteria for use in adulthood
ACTION: Brivaracetam formulary recommendation (adults) to be updated

9. Paediatric formulary RAG rating review: Phase 2 medicines used in endocrine, allergy and respiratory

The author presented this item, which aims to update the formulary RAG categories for paediatric medicines used in endocrine, allergy and respiratory in line with their actual use in practice. This is part of a larger ongoing project where a full review is being undertaken to consider the appropriate RAGG category for a medicine in paediatrics considering the different indications and specialties it may be used in and liaising with the relevant teams across SEL hospital trusts. This process is not being used to consider down recategorising of Red or Amber 3 medicines, which will remain the same. There are also existing Green, Amber 1 and Amber 2 medicines which are appropriate and do not require a change in RAGG category.

The table provided within the agenda pack summarises the drug class, the indications and the current and proposed RAGG categories. The majority of the medications reviewed, are being proposed to move from Green to Amber 1, Amber 2 or red. These patients may require specific monitoring on initiation and dose titration which is carried out by the specialist team. In general medications within the same class are assigned the same RAGG category, however there are some instances where 2nd or 3rd line agents and or those indications with little experience or use in paediatrics may be given a higher RAGG category meaning a greater amount of specialty input on initiation.

Overall, the proposals reflect current practice and the request to the Committee is to approve the proposed changes in RAGG category for the paediatric medicines used in endocrine, allergy and respiratory.

Clarification was requested regarding the change in RAGG categorisation for adrenaline and nebulised salbutamol from Green to amber 1 and how this would impact the supply of adrenaline or nebulised salbutamol for the management of medical emergencies within in a GP practice. GP committee members present confirmed GP practices keep stock of adrenaline and nebulised salbutamol as part of their emergency drugs supply which can be supplied to patients in the event of a medical emergency, and the Amber 1 RAGG category would not apply in this situation. The presenter agreed to amend the wording within the paediatric formulary to reflect this.

Committee members approved by consensus the proposed changes to the RAGG categories for paediatric medicines used in allergy, endocrine and respiratory.

ACTION: Paediatric formulary to be updated with approved RAGG category changes for paediatric medicines used in Allergy, Endocrine and Respiratory.

10. Guideline for the management of nightmare disorders in adults

The lead author of the guideline was not able to attend the meeting; however, a supporting colleague was in attendance to present this item. The guideline for the management of nightmare disorders in adults has been developed and consulted on locally following the April 2024 IMOC meeting where prazosin was approved in principle as Amber 2 for the management of nightmare disorder with disturbed sleep initiation in adults with post-traumatic stress disorder (PTSD). The formulary inclusion of prazosin as Amber 2 in this setting is based on the approval of a nightmare disorder pathway and updated co-morbid insomnia pathway.

In line with the proposed guideline, non-pharmacological interventions are recommended first line which includes optimising lifestyle factors and trialling Image Rehearsal Therapy (IRT) for at least 3 months. If no significant improvement is seen at 3 months with IRT, prazosin which is off-label in this setting is recommended as the first line pharmacological treatment. Trazodone which is also Amber 2 in this setting is recommended as the second line pharmacological treatment and agomelatine which is Red in this setting is recommended as the third line pharmacological treatment; both agents are recommended particularly when sleep initiation is disturbed.

Committee Members discussed the presented guide and it was noted that several comments from the IMOC team had been shared with the author prior to the meeting. Additional comments raised by

members included the removal of the statement which recommends the use of trazodone first line as this is not in line with the current co-morbid insomnia pathway, which requires an update to enable the first line use of trazodone. A comment was also raised in relation to how the on-going need for pharmacological treatment will be reviewed in this patient cohort, will patients remain under the sleep centre and be reviewed regularly and is deprescribing of treatments considered after a certain time of treatment. The presenter agreed to clarify this with the sleep consultants and the guideline will be updated to reflect this information.

Committee members approved by consensus the guideline for the management of nightmare disorders in adults pending amendments in line with the meeting discussions.

ACTION: Author to amend the guideline in line with meeting discussion and share with the IMOC team to progress for IMOC Chair's ratification

11. Formulary request for Pylera™ (bismuth 140mg/metronidazole 125mg/tetracycline 125mg) capsules for the treatment of H.pylori and prevention of relapse of peptic ulcers in patients with active or a history of H.pylori associated ulcers

The author was in attendance to present this item which is a formulary request to include Pylera™ (bismuth 140mg/metronidazole 125mg/tetracycline 125mg) capsules as Green for the treatment of H.pylori and the prevention or peptic ulcer relapse in patients with active or a history of H.pylori associated ulcers. Bismuth, which is one of the components of Pylera™, has had long term stock issues and is a treatment option for H. Pylori in patients who have previously failed H. Pylori triple therapy and a second line option in patients who have a penicillin allergy which is in line with guidance from NICE and Public Health England.

Pylera™ is a new triple therapy bismuth formulation in combination with two antibiotics recommended for the treatment of H.pylori – tetracycline and metronidazole which should be taken alongside a proton pump inhibitor as per national guidelines. This formulary request has been reviewed and virtually discussed by the SEL Forum for Antimicrobial Stewardship (SELFAS) and the group is in support of the formulary request.

The cost impact of including Pylera™ in the formulary is within the delegated financial threshold for the Committee. Based on current Drug Tariff prices, Pylera™ is more cost effective in comparison to prescribing each component separately if bismuth was available and this is based on the current price for tetracycline.

A comment was raised regarding the place in therapy for Pylera™, would it be used alongside other treatments or would it be used first line. The presenter clarified that for non-penicillin allergy patients, first line treatment will remain as per national guidance i.e. amoxicillin, clarithromycin and metronidazole, upon failing this treatment the addition of the bismuth would then be considered. However, for patients with a penicillin allergy the use of Pylera™ is considered sooner, as recommended by Public Health. Pylera™ is recommended as a first line treatment, taking into consideration if the patients has had previous exposure to antibiotics.

Committee members approved by consensus the formulary inclusion Pylera™ as green for the treatment of H.pylori and the prevention or peptic ulcer relapse in patients with active or a history of H.pylori associated ulcers.

ACTION: Pylera™ to be added with a RAGG category of Green the adult SEL JMF

12. Standing items/Items for information only

- Formulary submissions tracker

Noted.

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

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

- For information and noting:
- NICE TA review – TA1022: bevacizumab gamma for treating wet age-related macular and TA1004: Faricimab for treating visual impairment caused by macular oedema after retinal vein occlusion

The NICE TA reviews were noted by members. Small patient numbers are anticipated for bevacizumab use. For faricimab, local Trusts noted there will be use locally, based on the estimated cost modelling for implementation of the drug only (not service delivery) at one year, this will be above the committee's delegated financial threshold. In line with this, the costings at steady state are required from the Trusts so that the cost modelling can be escalated to the Executive Committee as per the Committee's Terms of Reference.

ACTION: Year on year cost modelling for faricimab in retinal vein occlusion to be provided for escalation to the Executive Committee

13. Any Other Business:

The ICB Medicines Safety lead outlined that in line with the various shortages with attention deficit hyperactivity disorder (ADHD) medicines, a local ADHD medication shortage memo was developed to support primary care and approved via the Committee's virtual triage panel. There has been many changes to the ADHD medication shortages with many now resolved; the Specialist Pharmacy Service (SPS) have developed material which supports primary care clinicians and signposts to relevant supporting information. Discussions with local GPs have taken place to gain their views on the need for the local ADHD medication shortage memo with the availability of the information provided by SPS. It has been concluded that the need for the local ADHD medication shortage memo is not necessary with the availability of the information available via SPS. Clinicians at SLaM and Oxleas also use and signpost to the SPS ADHD medication shortage information.

In line with this, it was proposed to Committee members that the local ADHD medication shortage memo be withdrawn. No objections were raised by committee members to the withdrawal of the local ADHD medication shortage memo.

IMOC dates for next 3 months:

Date	Time	Venue
Thursday 20 March 2025	2pm – 4:30pm	MS Teams
Thursday 17 April 2025	2pm – 4:30pm	MS Teams
Thursday 15th May 2025	2pm – 4:30pm	MS Teams