South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
Thursday 16th May 2024 (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. **Minutes, detailed action notes from the last meeting 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. Clarification will also be added in relation to the approval status of the continuous glucose monitoring guidance for children and young people with Type 1 diabetes to explain that the guidance will be accepted as final and published once approval from the Executive Committee is agreed. Members were provided with an update on progress against actions due for this month, these were noted, and items closed were agreed.

4. **SEL Overprescribing programme update**

   The Lead Pharmacist for the Overprescribing work programme presented an update on the overprescribing project and outlined information within the paperwork included within the agenda pack. The SEL Overprescribing sub-group developed a detailed workplan in response to the 3 year national program to tackle overprescribing, including: a focus on transfer of care, expanding structured medication reviews, improving sustainability, inclusion of deprescribing into clinical guidelines, workforce education and training, engaging with partners on mini-projects and interventions, and engaging with patients and the public. Projects were conducted in each of the focus areas with positive findings and key learning outcomes in each area identified.

   Learning from each mini-project highlighted that there is a need for a systems approach to tackle overprescribing as there are complex interdependencies. It was found that people across the system were willing to engage and contribute to the workplan to reduce overprescribing. Progressing ahead, a reliable and credible methodology for demonstrating savings and scaling up approaches exhibited in the mini-projects is needed to move the project forward. There are several workplans in place to progress the overprescribing agenda, including the use of metrics and dashboard data.

   In response to a query regarding the future plans for the project following the end of the lead overprescribing role, the presenter confirmed that a range of Care and Clinical Professional (CCPL) roles have been recruited to by the Integrated Care Board (ICB), one of which includes the Lead Overprescribing Pharmacist role, for a limited number of hours per week. This will provide some continued leadership and support to the programme. The Chair highlighted that the SEL overprescribing work had received recognition by being shortlisted as finalists in the Clinical Pharmacy Congress 2024 awards and congratulated the presenter.

   Members noted that raising awareness of the magnitude of ongoing work is important. The Committee thanked the presenter for the valuable update on the Overprescribing programme of work.

5. **Update on the financial status related to prescribing and medicines in South East London**

   The ICB Chief Pharmacist updated members on the financial status in SEL in relation to medicines and prescribing. As a healthcare system, the current financial position is challenging with recovery plans in place. In this context, prescribing budgets across the system are also financially challenged. As a Committee, whilst there is currently no change to the financial threshold delegated to the Committee. It is encouraged that the Committee prioritise value and outcomes, alongside investment in medicines for managing long term conditions (LTCs) in all workstreams.

An update was also provided on the ICB restructure, which aimed to reduce its management costs by 30% and incorporated a reduction of 15% in the Medicines Optimisation team. An enhanced collaborative approach across SEL and Place (borough) has been established as part of the restructure. As a result it is recognised there is reduced capacity across the system, additionally, the Trusts also face workforce pressures. In view of this, it is important to reduce duplication and make use of existing guidance to reduce the resources needed to develop and update guidelines. Consideration will be needed for existing guidance and whether specific pieces of guidance are still required/relevant or could be retired, for example, where national guidance exists. Digital solutions will also need to be explored. The Chair suggested it would be helpful for Committee members to be sighted on the new ICB Medicines Optimisation Team structure.

ACTION: Updated ICB Medicines optimisation staff structure to be shared for information in a future agenda pack

6. Updated formulary recommendations for approval

- **Formulary recommendation 130 - Hydrocortisone (Alkindi®) granules in capsules for replacement therapy of adrenal insufficiency in infants and children (neonates – 5 years old)**

Following discussion and agreement at the last meeting, the associated formulary recommendation has been updated to remove the time limited approval. No feedback was received via the virtual Triage Panel review process. The Committee approved by consensus the updated formulary recommendation.

- **Formulary recommendation 105 - Testosterone in topical gel formulation for use in women with decreased libido in the menopause**

Following approval of the SEL menopause guidance in November 2023, the associated formulary recommendation has been updated to reflect the agreement at the November 2023 meeting to recategorise testosterone gel category from Amber 2 to Amber 1. It was noted that Testim™ 1% gel has been discontinued, therefore is not included in the recommendation update and will be removed from the SEL Acute Provider Collaborative's (APC) menopause guidance.

The Committee approved by consensus the updated formulary recommendations.

7. Formulary application for Ryaltris™ (olopatadine and mometasone) nasal spray for adults and adolescents 12 years and older for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis

This formulary submission originates from a consultant ear, nose and throat surgeon at GSTT. The application requests the use of Ryaltris™ as an alternative to Dymista™ for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis in adults and adolescents aged 12 years and older. The application requests to use Ryaltris™ under a Green "Red, Amber, Green, Grey" (RAGG) category and as per the following criteria which is in line with the criteria for use of Dymista™:

- Confirmed diagnosis of allergic rhinitis (with skin prick testing or allergen specific [RAST] testing as per standard protocol) with associated nasal symptoms.
- Prior treatment with oral antihistamines and intranasal steroids has failed.
- Patient education on proper application technique, potential side effects, and precautions.
- Establishing a clear treatment plan with the GP for ongoing use in the community or in patients with allergic rhinitis who have demonstrated intolerance of an alternative nasal treatment such as Dymista™ nasal spray.

➢ **Evidence Review**

The formulary pharmacist provided an overview of the evidence base and background to the condition. A detailed evidence review was provided within the meeting agenda pack covering background to the condition, a review of the evidence base with strengths and limitations and rationale for use of Ryaltris™ in this setting. The information presented also included the estimated resource impact for use of Ryaltris™. The resource impact of the submission is within the financial threshold that the Committee has delegated authority to approve.

Intranasal corticosteroids are widely recognised as the most effective symptomatic treatment available for allergic rhinitis. Intranasal antihistamines have the fastest onset of action (within minutes) but are less effective than intranasal corticosteroids. First-line treatment options are usually intranasal corticosteroids and antihistamines, either alone or in combination. Ryaltris™ is a combination of intranasal antihistamine (olopatadine) and corticosteroid (mometasone) licensed in the UK in 2021 for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis in adults and adolescents aged 12 year and above. The National Institute for Health and Care Excellence (NICE) has not reviewed Ryaltris™. However, the Scottish Medicines Consortium (SMC) accepted it in 2021 for use within Scotland in adults and adolescents aged 12 years and above for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis, for use where monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.

With respect to the evidence base, three efficacy and safety studies were reviewed by the Swedish medicines regulatory agency and accepted for license within the EU via the mutual recognition process. The studies were randomised, double-blind, placebo-controlled, and parallel-group in design. Two of these randomised controlled studies (RCTs) demonstrated that treatment with Ryaltris™ resulted in significant and clinically meaningful improvements in seasonal allergic rhinitis (SAR) nasal symptoms compared to placebo, and olopatadine. One of these RCTs demonstrated Ryaltris'™ superiority over mometasone (measured by average morning and evening12-hour reflective Total Nasal Symptom Score [rTNSS]). However, this effect was not seen in the second trial where statistical significance was not reached and the authors were unable to determine the cause of the non-significant result. Both studies did, however, demonstrate that symptom improvement with Ryaltris™ was rapid (15 minutes) and sustained for 14 days of treatment, and improvements in each of the individual nasal symptoms. The studies also demonstrated that these improvements in nasal symptoms were considered clinically meaningful. Overall, Ryaltris™ is well tolerated, with the main side effects being dysgeusia, epistaxis and nasal discomfort.

- **Applicants' presentation**

The applicant was in attendance to present the submission and answer questions. The applicant's declaration of interest was noted. It was stated that the application was being submitted as an alternative combination spray to Dymista™. Experience has found Dymista™ to be useful because in combination it improves compliance and also effectiveness as only one spray product is needed to deliver the two medicines. Ryaltris™ has slightly different components but the same effect and would be useful for cases where Dymista™ was not tolerated, for example because of taste. Because of the different intranasal corticosteroid, Ryaltris™ may sometimes be appropriate for first line. The applicant noted there may have been a further price reduction for Ryaltris™, although it was not clear if this was a hospital only procurement discount.

In response to a query relating to the difference in the estimated patient number expected to be started at the hospital sites, the applicant advised the Committee that some sites do not have an allergy service and prescribe without testing, and some do have an immunology and allergy service, which may lead to differences in prescribing. It was also clarified that allergy testing is not routinely carried out in primary care for seasonal allergic rhinitis. In patients who have not had allergy testing and who fail on either Ryaltris™ or Dymista™, a referral to secondary care would be required in line with current SEL practice. The applicant also clarified that both Ryaltris™ and Dymista™ are intended to be included on the formulary as equivalent alternatives. The prescribing clinician would need to use clinical judgment to decide on the best option for their patient. Members noted that if approved, Ryaltris™ would need to be included in the SEL APC's ENT guidance – both the adult and paediatric guidance. The applicant also advised that in seasonal allergic rhinitis, the use of Ryaltris™ is not expected to be long term. Only a small percentage of patients would require longer term treatment for perennial rhinitis.

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

Members discussed the application, and it was felt that there was a benefit for the inclusion of Ryaltris™ onto the formulary as an additional option. It was felt that the price needed to be clarified, following the authors comment and a clear place in therapy determined. The Committee approved by

consensus the addition of Ryaltris™ to the formulary under a Green "RAGG category, subject to clarification on the place in therapy and cost of the product.

ACTION: Formulary recommendation to be drafted and presented at a future meeting once there is clarity on the criteria for use and cost.

Post meeting note: *The lead formulary pharmacist confirmed that the lower cost is a confidential commercial agreement for hospitals only. The price of Ryaltris™ in primary care is as per the list price in the Drug Tariff. The applicant agreed that Ryaltris™ and Dymista™ would be equal treatment options at the same point in therapy, with the choice determined by the prescribing clinician. This place in therapy is supported by the clinical lead for the APC's ENT guidelines (adult and paediatric).*

8. **Updated sleep pathway: Pharmacological management of excessive daytime sleepiness due to narcolepsy (with or without cataplexy) and associated formulary request for combination use of solriamfetol and sodium oxybate in type 1 narcolepsy**

This item is being re-presented to the Committee following discussions at the December 2023 IMOC meeting. The extract of the minutes from the December 2023 meeting were included in the meeting paperwork to remind members of the previous discussions. The Specialist Sleep Pharmacist from the local sleep service was in attendance to present the item.

An abridged formulary request for the combination use of solriamfetol and sodium oxybate in type 1 narcolepsy (narcolepsy with cataplexy) forms part of the re-presentation to the Committee, supported by an evidence briefing included in the agenda pack. The formulary pharmacist summarised the evidence base and background to the condition. In 2022, NICE Technology Appraisal (TA) 758 approved the use of solriamfetol for excessive daytime sleepiness in narcolepsy, restricted to use where modafinil and an amphetamine based stimulant have not worked well enough or are not suitable. As the pivotal trials did not cover combination treatment with other agents for narcolepsy the NICE TA does not include recommendations on the use of solriamfetol as part of a combined treatment regimen.

Sodium oxybate is licensed for use in narcolepsy with cataplexy, and can treat excessive daytime sleepiness and cataplexy symptoms, however clinical experience from specialists indicate that it is useful for treating cataplexy. European guidance for narcolepsy recommends separate management approaches for patients with narcolepsy with and without cataplexy. For patients with predominantly cataplexy symptoms, sodium oxybate is recommended first line, with solriamfetol being a potential additive treatment at second line. For patients with predominantly daytime sleepiness symptoms, the guidance recommends solriamfetol as one of the first line options, and sodium oxybate as a potential additional agent in the second line setting. The current SEL narcolepsy and cataplexy pathways detail a slightly different treatment strategy and recommend use of sodium oxybate for patients with cataplexy, rather than for managing excessive daytime sleepiness. Cataplexy and excessive daytime sleepiness symptoms are managed via different pathways. Patients taking solriamfetol who have, or develop cataplexy symptoms, require a different agent to treat this separate symptom. If the existing SEL cataplexy management pathway were followed, sodium oxybate appears as a third line option.

With respect to the evidence base, there are minimal published data describing the concurrent use of solriamfetol and sodium oxybate for narcolepsy with cataplexy (including whether the sodium oxybate is being used for cataplexy specific symptoms, excessive daytime sleepiness, or both). This is potentially due to the small patient numbers involved due to the rarity of the condition. The two observational studies identified did not include outcome data specific to this combination of treatment, although they suggest the combination is effective.

Data from these observational studies, the recommendations in the European guidance, and other review articles, demonstrate that combination treatment with solriamfetol and sodium oxybate is considered an appropriate treatment strategy for narcolepsy with cataplexy by a significant number of specialists, despite the lack of direct evidence base.

The resource impact of the request is within the financial threshold that the Committee has delegated authority to approve.

Members queried how combination use would be RAGG categorised on the formulary since solriamfetol is categorised as Red (hospital only) and sodium oxybate as Amber 3 (shared care). In response, the presenter recommended that the combination be used under a Red RAGG category and be noted on the formulary as such. Combination prescribing would remain under the specialist sleep service. The presenter clarified that treatment choice would depend on the prevailing symptom. If excessive sleepiness is a predominant feature, then the first line treatment option would be solriamfetol and in patients with cataplexy as the predominant symptom, the choice would be sodium oxybate. In patients already being treatment with sodium oxybate, the sequential order of treatment is determined on a case by case basis, depending on the patient's symptomology at the time.

Members requested that the pathway is further clarified so that the place in therapy of each treatment and treatment steps with individual or combination treatment are robustly defined. Furthermore, it was noted that as pitolisant is an effective treatment for both cataplexy and narcolepsy, it could be highlighted as a preferred treatment in narcolepsy for people with cataplexy. There was also a suggestion to either separate both pathways within the same document or include a separate arm for combination treatment for clarity. Another option suggested was to remove sodium oxybate from the excessive daytime sleepiness pathway altogether and keep it within the cataplexy pathway and each pathway could cross reference to the other to avoid confusion. The presenter outlined that type 1 narcolepsy is narcolepsy with cataplexy and type 2 narcolepsy has no associated cataplexy. Additionally sodium oxybate is not licensed for type 2 narcolepsy. In view of this, taking sodium oxybate out of the excessive daytime sleepiness pathway would be a good option for consideration, possibly under a single document. It was agreed that the pathway should include a note highlighting that combination use of solriamfetol and sodium oxybate is not covered by the NICE TA.

Members discussed the formulary request and noted that whilst the evidence base is limited, use is in a small number of patients where clinical rationale will be applied on a case-by-case basis for treatment under a specialist centre only. A final decision was deferred pending a revised pathway being presented back to the Committee in the future in line with discussions and a proposed approach for the RAGG category. Until this is completed, the combination use of these agents remains non-formulary.

ACTION: Pathway to be revised by authors in line with discussions and presented at a future meeting

9. Daridorexant in the treatment of short term insomnia: Agreeing the use of NICE Clinical Knowledge Summaries (CKS) insomnia summary to support daridorexant prescribing in SEL

Following previous discussion at the December 2023 IMOC meeting, the Committee were asked to decide if the NICE Clinical Knowledge Summaries (CKS) insomnia topic would be helpful and sufficient in supporting primary care clinicians in the prescribing of daridorexant. In line with earlier discussions in the meeting, this would avoid duplication of effort required in producing an additional supporting resource, such as an information sheet. The Senior Sleep Pharmacist remained in attendance from the previous item and agreed that the insomnia CKS topic contained sufficient information.

Committee members agreed by consensus to the use of the NICE CKS insomnia summary to support daridorexant prescribing and that development of a local information sheet would not be required. The SEL formulary entry for daridorexant already signposts users to the CKS insomnia topic.

10. Updated guideline for Medicines Optimisation in Bariatric and Metabolic Surgery & associated cost profile

A consultant endocrinologist was in attendance to present this item alongside a specialist acute Trust Pharmacist, supported by the Borough lead Pharmacist and Formulary Pharmacist. The updated guideline was presented at last month's meeting, in line with discussions requested changes have been made to the guideline and presented alongside the cost modelling profile. The first line multivitamin choice was discussed, and presenters highlighted that Sanatogen A-Z™ provided a cost

saving when compared to Forceval™, however due to the vitamin A content of Sanatogen A-Z™ it is not suitable for pregnant women or those of childbearing age. Patients with chronic kidney disease (CKD) and an estimated glomerular filtration rate (eGFR) below 45ml/min are not suited to Sanatogen A-Z™. It was agreed that Sanatogen A-Z™ could be recommended first line within the guidance with the exemptions of pregnant women or those of childbearing age and patients with CKD and an eGFR below 45ml/min, in these patients Forceval™ would be the multivitamin of choice. It was noted that the estimated cost impact associated with this guidance is within the Committee's delegated financial threshold.

As part of the Committee's discussions, the authors agreed to clarify which element of the guidance were intended for primary care by including a small box outlining the key responsibilities for primary and secondary care. The Committee agreed that women under 55 without hysterectomy should be recommended to be prescribed Forceval™ rather than counselled to approach their prescriber to be switched if they became pregnant. Some formatting and minor grammatical suggestions will be shared with the authors outside of the meeting.

Committee members agreed by consensus to approve the guideline pending amendments in line with discussions.

ACTION: Authors to update the guideline and share with IMOC team to progress for ratification via Chair's action

11. SEL primary care prescribing guide for ocular lubricants for the treatment of dry eyes in adults

The Borough lead presented this item. The guide has been adapted from the pan-London dry eyes guidance. Each section of the guide was briefly described, and it was noted that in light of the national and local guidance on encouraging self-care, the guide has differentiated the severity of dry eye conditions and notes that only patients with severe dry eyes will require prescribed treatment. Patients with mild or moderate dry eye conditions are signposted to self-care using lifestyle and over the counter treatment options. Information to support this has been provided within part 1 of the guidance. The guide includes information on diagnosis, treatment pathways & recommendations, frequently asked questions and examples of branded products.

In relation to the cost-effective brand section, members noted that a number of brands are listed in the table. A Joint Medicines Formulary operates across primary and secondary care in SEL and the formulary generally notes dry eye products generically. Having a number of brand names could be confusing from a formulary perspective, as all the brands are not listed in the formulary. Furthermore when prices change or there are shortages, the table would need regular updates to reflect the most cost-effective brands. The presenter agreed to remove brand names and focus on providing generic options with signposting to community pharmacy for over the counter (OTC) self-care options. For patients who require a prescription, the OptimiseRx prescribing decision support tool could be considered for primary care, to enable the most cost-effective formulary option to appear on the prescribing system as first-choice. It was also suggested that the formulary website could note the products generically rather than stating specific brands with an accompanying statement that the most cost-effective product should be used. This would allow more flexibility in choice of products as prices change and hospital contracts are updated.

In relation to exceptions, the existing information regarding the two general exceptions to self-care in the NHS England (NHSE) self-care guidance regarding treatment of adverse effects for symptoms of a more complex illness and managing a long-term condition will be made more prominent. Members acknowledged that these two exceptions mean that patients might be prescribed the drops for longer term use and continued prescribing would be via the GP and would not be suitable for switching or for self-care. Due to time constraints, it was noted that further comments and formatting changes would be shared with the author outside of the meeting.

Committee members agreed by consensus to approve the guideline pending amendments in line with discussions and consideration of comments to be shared outside of the meeting

ACTION: Authors to update the SEL primary care prescribing guide for ocular lubricants and IMOC team to progress for ratification via Chair's action

12. Standing Items /Items for information only

- Formulary submissions tracker

Noted.

- NICE TA Guidance Summary - ICS & NHS England attributed medicines:

The summary was noted, and RAGG categories were agreed by consensus.

- For information and noting:
- RMOC update – Nil for this meeting (Committee is stood down)
- Adult and paediatric formulary updates - noted by Committee members

13. Any other business

The Chair informed the Committee that, as a result of the ICB reorganisation, the Southwark borough Medicines Optimisation representative has stepped down as a Committee member. The member was not in attendance at this meeting, but the Chair has, on behalf of the Committee, passed on thanks and acknowledgement for their contributions.

IMOC dates for next 3 months

Date	Time	Venue
Thursday 20th June	2pm-4:30pm	MS Teams
Thursday 18th July	2pm-4:30pm	MS Teams
Thursday 15th August	2pm-4:30pm	MS Teams