South East London Integrated Medicines Optimisation Committee
17 March 2022 (Meeting held via MS Teams)
Final Minutes

1. Welcome, introductions and apologies

The Chair welcomed attendees to the meeting followed by a round of introductions. 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 annual declarations be returned. No conflicts were raised.

3. Detailed action notes of the last meeting, minutes and action log:

The minutes were accepted as an accurate record pending corrections to a few minor grammatical typos. Members were provided with an update on progress against actions due for this month, these were noted, and items closed were agreed.

4. Outcome's data report for botulinum toxin type A for spasmodic dysphonia (laryngeal dystonia) in adults

The authors were in attendance to present this item. In line with the formulary submission approval of botulinum toxin type A for spasmodic dysphonia (laryngeal dystonia) in adults at the October 2020 MPRG meeting, the applicants updated the Committee on patient numbers and outcomes following one year of use. Nine patients have been treated with botulinum toxin over a 20 month period with majority of patients receiving 1.5 units of botulinum toxin injection administered to the vocal cord every 3 months. Overall, 7 out of 9 patients have experienced a good response and continue on treatment. There have been no side effects experienced by patients. The team hope to publish the full audit report which was included in agenda pack.

A comment was raised regarding the low patient numbers in comparison to the estimated patient numbers within the original formulary application. Committee members noted the main contributor for low patient numbers has been the COVID-19 pandemic and patient numbers are anticipated to increase as business as usual returns and more patients are referred to the tertiary service.

The Committee thanked the authors for presenting the outcome data.

ACTION: GSTT internal guideline for botulinum toxin type A for spasmodic dysphonia (laryngeal dystonia) in adults to be shared with Committee
ACTION: Formulary recommendation to be updated.

5. Updated South East London hypertension management guidance

The author was in attendance to present this item. Updates to the guideline were summarised to the Committee as detailed in the agenda pack. The author has also reviewed the draft updated NICE hypertension guideline and confirmed the minor updates to the NICE guideline do not impact on the current updated local hypertension guideline. Committee members raised some minor comments, for example a request to include a glossary of terms was made, which the author will review.

The Committee ratified the guideline by consensus pending updates in line with the discussion.

ACTION: Guideline to be updated as per discussion and progressed for ratification via Chair's action

6. Formulary recommendations:

New: Doxylamine succinate 10mg/pyridoxine hydrochloride 10mg tablets (Xonvea™) for treatment of nausea and vomiting in pregnancy in those intolerant of or failing on first line antiemetics

- Update: Recommendation 092 - Levonorgestrel 52mg (20 micrograms/24 hours) Intrauterine Delivery System (Levosert®) for the treatment of heavy menstrual bleeding and contraception and Levonorgestrel 19.5 mg Intrauterine Delivery System (Kyleena®) for contraception

A Committee member raised a comment regarding the licensing of Levosert®, which is not licensed as HRT for women who are peri-menopausal/menopausal and experience heavy menstrual bleeding, however Mirena® is licensed in this setting. Committee members agreed it would be useful to add a comment within the formulary recommendation to reflect this.

The Committee ratified the formulary recommendations by consensus pending updates to recommendation 092.

ACTION: Recommendation 092 formulary recommendation to be amended as per discussion and progressed for ratification via Chair's action

7. Updated medicines section of Clinical Effectiveness South East London (CESEL) Diabetes guide for General Practice (GP)

The author was in attendance to present a minor, interim update to the Diabetes Guide following publication of updated NICE type 2 diabetes guidance. An advisory cautionary statement developed by the CESEL team and the IMOC diabetes subgroup to highlight to users that the medicines section of the CESEL guide is being updated has been added to the CESEL guide.

Committee members were requested to consider whether the same advisory cautionary statement can be used as standard wording for future CESEL guides which require an update to the medicines section due to updated NICE guidance, without the cautionary wording requiring submission and approval by the SEL IMOC each time. Committee members agreed this process by consensus.

Committee members approved the updated CESEL guide with the advisory cautionary statement by consensus.

8. Updated South East London Inflammatory Bowel Disease pathways
Updated escalated anti-TNF dosing in Crohn's disease proposal

Following presentation at the last IMOC meeting the author was in attendance and presented the amendments made to the items in line with the discussion at the February 2022 SEL IMOC meeting.

A comment was raised regarding the development of a document for Committee members suggested it would be helpful for clinicians to have access to the agreed criteria for use for the two areas via the SEL IMOC website. Committee members also requested that outcome data are presented back in 12 months. The author was happy with both requests.

Committee members approved the updated proposal and IBD pathways by consensus

ACTION: Separate document detailing criteria for use of dose escalated anti-TNF therapy and dual biologic therapy in CD to be developed and progressed for ratification via Chair's action.

9. Request to remove the suspension of ulipristal 5mg tablets and to allow prescribing with further restrictions due to risk of serious liver injury in line with latest MHRA recommendation

The Formulary Pharmacist presented this item, requesting the formulary inclusion of ulipristal 5mg tablets (Esmya™) for patients managed at LGT only who are unable to receive treatment for uterine fibroids surgically or with GnRH injections following removal of the temporary licensing suspension of ulipristal 5mg tablets.

LGT will be retaining the prescribing and monitoring of all patients initiated on ulipristal 5mg tablets (Red listed medication) and are estimating low patient numbers. GSTT and KCH confirmed their clinics do not have the capacity and infrastructure to take on the safe prescribing and monitoring of ulipristal.

Comments were raised regarding the procedures in place to ensure the safe prescribing and monitoring of ulipristal 5mg tablets at the Trust. The Committee noted there should be a written agreement between the clinician and patient to ensure patients understand the need to attend blood test appointment at all times and the importance of communicating to GPs when patients are initiated on this treatment.

Committee members agreed by consensus assurance was required regarding the processes which will be in place to manage and mitigate any patients who miss blood tests for the monitoring of ulipristal 5mg tablets before any final decision can be taken.

ACTION: To be re-presented at a future meeting to provide reassurance on how missed blood tests for LFT monitoring will be managed

10. Rivaroxaban for the treatment of venous thromboembolism (VTE) in paediatrics (aged less than 18 years old)

This formulary submission has been submitted by a Consultant Haematologist and Specialist Clinical Pharmacist at Evelina. The application requests for the use of rivaroxaban as an alternative first line treatment option of venous thromboembolism (VTE) in paediatrics. Rivaroxaban is the only licensed treatment for this indication, off-label warfarin and low molecular heparin are the current anticoagulation options for this patient cohort. The dosing of rivaroxaban for VTE in paediatrics is weight based and will generally be prescribed up to 3 months, however it is anticipated approximately 25% of patients will require longer term treatment beyond 3 months.

- **Evidence review**

The Formulary Pharmacist presented an overview of the efficacy and safety evidence for the use of rivaroxaban in this setting which was provided within the agenda pack. The information presented also included the estimated resource impact for rivaroxaban, this is based on a cost comparison between 12 months of rivaroxaban treatment in patients above 30kg and 12 months of treatment with warfarin suspension at a dose of 3mg; based on the cost estimates, overall drug costs for implementing rivaroxaban could be cost neutral. Savings are expected as patients will not be required to attend INR monitoring clinics. The resource impact of the submission is within the financial threshold that the Committee is authorised to approve.

- **Applicant's presentation**

The Consultant Haematologist and Associate Chief Pharmacist for Children's services from Evelina London Children's Hospital were in attendance to present the submission on behalf of the applicants and field any questions. The declaration of interest for the applicant and presenters were noted. The presenters confirmed the use of rivaroxaban in this setting will remain with the specialist team for all patients at the Evelina (Red categorisation), but they would also like to request approval to categorise rivaroxaban as Amber 3 (shared care) for those patients requiring longer term treatment (greater than 3 months). The presenters clarified that the request for the amber 3 category would be for IMOC to consider after some experience in use has been gained under hospital only use – with a suggested timeframe for data to come back to Committee after 6 months l (after October 2022).

- **SEL IMOC discussion after departure of presenter:**

Committee Members discussed the importance of patients being able to receive their prescriptions and monitoring for rivaroxaban locally. However, once experience in use has been gained by the Trusts, the outcome data would need to be presented back to the Committee to inform a decision on whether shared care would be appropriate for this patient cohort.

Members agreed by consensus a Red category (specialist or hospital prescribing only) alongside outcome data to be presented back to the Committee by December 2022. The data will support further discussions on categorising use in longer term patients as amber 3 (shared care).

ACTION: Formulary recommendation to be drafted.

11. Progress with the SEL IMOC work plan for 21/22

Committee members noted the final IMOC work plan report for 21/22. No comments were raised by Committee members.

12. Updated rheumatology pathways and cost tool

The authors were in attendance to present the updated rheumatology pathways, cost tools and proposal for the use of dose escalated guselkumab for the management of psoriatic arthritis (PsA).

- Seronegative spondyloarthropathies (SpA) pathway, Rheumatoid arthritis (RA) pathway and cost tools.

The updates to the pathways and cost tool were highlighted within the agenda pack which included the addition of the Shringrex® vaccine in line with Department of Health guidance, signposting to MHRA drug safety alerts and upadacitinib for the management of moderate rheumatoid arthritis and psoriatic arthritis in line with NICE TAs 744 and 768.

- Proposal for use of dose escalated guselkumab in psoriatic arthritis (PsA) in South East London

Dose escalated guselkumab is being requested in line with the SpC for PsA patients at risk of joint damage. Dose escalated guselkumab will be used within a locally agreed criteria as outlined within the proposal which includes the assessment of response to treatment and the stopping criteria. The proposal also aims to prevent the need for submission of IFRs given there is a patient cohort.

Patient numbers will be low, and the monitoring and outcomes will be undertaken through the rheumatology subgroup. The resource impact of the proposal is within the financial threshold that the Committee is authorised to approve.

It was noted that in line with information from NICE, the resource impact from the two new NICE TAs is unlikely to be significant. Committee members approved the pathways (pending updates to the SpA pathway in line with the discussion), cost tools and the use of dose escalated guselkumab in PsA by consensus.

ACTION: SpA pathway to be updated as per discussion and documents to be progressed for ratification via Chair's action

13. The identification, treatment and management of malnutrition in adults, including the appropriate prescription of oral nutrition supplements (ONS)

Following presentation at the last IMOC meeting the author was in attendance to re-present the guideline with support from the Lewisham borough Deputy of Medicines Management. The guide has been updated as per discussions from the February 2022 SEL IMOC meeting.
A comment was raised regarding the hyperlinks for the patient resources within the guideline, the author confirmed the patient resources will be uploaded to a newly created web page on the SEL CCG website and then hyperlinked within the guideline. Southwark borough agreed to support the authors with this.

Committee members approved the guidance by consensus.

ACTION: Lewisham borough to liaise with Southwark borough regarding the creation of an ONS webpage on the SEL CCG website. Once created, guideline to be uploaded to the IMOC webpages.

14. Follow up data for shared care guidance on the use of Sativex™ to treat severe spasticity associated with multiple sclerosis (MS) in adults

The author was in attendance to present this item with support from the relevant Formulary Pharmacist. The follow up data and shared care implementation process for Sativex™ was presented to the Committee in line with the report within the agenda pack.

Overall, 22 patients have been initiated on Sativex™ across SEL for the management of severe spasticity associated with MS since the recategorisation of Sativex™ from Red to Amber 3 and the approval of the shared care guideline in March 2021. There has been 1 GP refusal (from SEL) to take on shared care for Sativex™ despite input and support from the borough medicines management team. . No safety incidents in primary care were observed. The Committee noted Bexley GPs tend to take on Sativex™ shared care on an individual case by case basis. An updated shared care guideline was also presented to the Committee – a minor update has been made to specialist contact details.

A comment was raised regarding the rationale behind LGT initiating more patients on Sativex™ in comparison to KCH and GSTT. The author confirmed KCH and GSTT have been prescribing Sativex™ for MS prior to the development of the shared care guideline. There are also some KCH patients who are yet to be transferred to shared care due to the COVID-19 pandemic..

Committee members supported the continuation of the existing shared care arrangements for Sativex™ to treat severe spasticity associated with MS in adults and the shared care guideline review date will be extended by 2 years. The updated shared care guideline was approved. The position statement will be updated to remove the reporting requirement.
ACTION: Position statement to be updated.

15. Standing items

- Formulary submissions tracker

Noted.
NICE Technology Appraisal Guidance Summary The summary was noted and Red, Amber, Green, Grey (RAGG) categories were agreed by consensus for NICE TAs published since the last meeting.

IMOC dates for next 3 months

Date	Time	Venue
21st April 2022	2:00pm – 4:30pm	MS Teams
19th May 2022	2:00pm – 4:30pm	MS Teams
16th June 2022	2:00pm – 4:30pm	MS Teams