South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
19th January 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 action notes and minutes were accepted and approved as an accurate record pending corrections to 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. (i) Penicillamine for treatment of Wilson's disease in adults and paediatrics shared care guideline

(ii) Formulary inclusion of pyridoxine for the prevention of penicillamine-induced neuropathy in Wilson's Disease

The authors were in attendance alongside the Borough Lead to present this item. Development of this shared care guideline (SCG) was approved by the Committee last year following a request to the Committee to recategorise penicillamine for the management of Wilson's disease in adults and children. Alongside the SCG approval, Committee members are also being requested to consider the paediatric formulary inclusion of pyridoxine for the prevention of penicillamine-induced neuropathy in Wilson's disease.

Comments were raised regarding clarification points in relation to the transfer of care process and monitoring requirements in primary care, including an update to the SCG outlining that the first year of prescribing and monitoring as described by the author at the meeting. will be undertaken in secondary care and the specific monitoring required for renal function and signs of adverse effects. Clarification within the SCG for the dosing considerations associated with pyridoxine when a patient transitions from paediatric to adult service was also requested alongside acknowledgment within the SCG that the recommended dosing for pyridoxine is different to the licensed dosing but in line with local expert opinion and practice.

Committee members approved the SCG and formulary inclusion of pyridoxine for the prevention of penicillamine-induced neuropathy in Wilson's disease by consensus pending updates as per the discussions.

ACTION: Author to update the SCG in line with discussions and progress for IMOC Chair's ratification.
ACTION: Pyridoxine for the prevention of penicillamine-induced neuropathy in Wilson's disease to be added to the paediatric formulary with detail as per discussions

5. (i) Updated sleep pathways, shared care guidance and supporting resources:
- **Pathways for the pharmacological Management of Non-REM Parasomnia, REM Behaviour Disorder and cataplexy associated with narcolepsy**
- **Shared care prescribing guideline for the prescribing and monitoring of stimulant therapy and anti-cataplectic agents in the management of narcolepsy (+/- cataplexy) and idiopathic hypersomnia in adults**
- **Information for GP's and community pharmacies and medicines information leaflet for REM Behaviour disorder and Non-REM parasomnias**

(ii) Formulary inclusion of venlafaxine immediate release tablets to the formulary for use in cataplexy (off-label)

The author was in attendance to present these items, which have had minor updates in line with the summary of changes provided in the agenda pack. Committee members agreed that in view of the minor changes it was acceptable to review and consider these documents for approval without a broader consultation. Committee members were also requested to consider the formulary inclusion of

immediate release (IR) venlafaxine for the management of cataplexy associated with narcolepsy as part of the presentation.

The minor updates to the pathways, SCG and supporting resources were outlined to Committee members in line with the summary of changes provided in the agenda pack. The formulary inclusion for IR venlafaxine for the management of cataplexy associated with narcolepsy is an off-label indication and provides a treatment option for patients with predominantly daytime symptoms where modified release venlafaxine (which is already formulary included for this indication) often worsens the sleep quality in this patient cohort and may cause RLS.

Comments were raised in relation to the SCG including whether the risks associated with modafinil during pregnancy will be regularly discussed with patients. The author clarified these risks will be checked with patients on a minimum of an annual basis. Additional comments raised included the need for annual monitoring of blood pressure and heart rate with fluoxetine, the author clarified this is only for patients on multiple medications for the management of their blood pressure or if patients are on other concomitant medications that might prolong QTc interval and would be made clearer in the SCG.

Committee members approved the updated pathways, shared care guideline, supporting resources and formulary inclusion of venlafaxine IR for the management of cataplexy associated with narcolepsy as Amber 3 by consensus pending updates to the documents in line with the discussions.

ACTION: Author to update the pathways and shared care guideline in line with discussions and progress for IMOC Chair's ratification
ACTION: Venlafaxine IR for the management of cataplexy associated with narcolepsy to be added to the SEL JMF

6. Local implementation of NICE TA 832 relugolix-estradiol–norethisterone acetate (Ryeqo™) for treating moderate to severe symptoms of uterine fibroids

The Formulary Pharmacists presented this item which outlines the local implementation and desired Red, Amber, Green, Grey (RAGG) categorisation for NICE TA 832 relugolix-estradiol–norethisterone acetate (Ryeqo™) for treating moderate to severe symptoms of uterine fibroids. The likely place in therapy for Ryeqo™ is after injectable gonadotrophin releasing hormone (GnRH) analogues (such as Zoladex™) in patients unable to tolerate GnRH analogues or where surgery is contraindicated/not a preferred treatment option for the patient. The desired RAGG category is Amber 2 (specialist initiates and provides first prescription). The number of patients treated with Ryeqo™ is likely to increase overtime, however in line with the NICE TA resource impact statement Ryeqo™ is not expected to have a significant resource impact as Ryeqo™ is an additional treatment option available at a similar price to current treatment options. In the longer term, there may be savings from reduced use of resources to administer the injectable treatments.

A comment was raised regarding clarification and agreement by the specialist teams as to whether primary care or secondary care will be responsible for referring patients for a DEXA scan after one year of treatment. The formulary leads will clarify this – it should be made clear at the point of transfer where the responsibility lies.

Committee members approved relugolix-estradiol–norethisterone acetate (Ryeqo™) as Amber 2 with a minimum of one month supply from the hospital by consensus.

ACTION: Relugolix-estradiol–norethisterone acetate (Ryeqo™) for treating moderate to severe symptoms of uterine fibroids to be added to the SEL JMF as Amber 2 with a minimum of one month supply from hospital specialist team
ACTION: Trust formulary leads to follow up DEXA scan requirements

7. SEL IMOC workplan Q3 2022/23 update

The SEL IMOC workplan was presented with progress noted on timescales for particular workstreams. It was noted that the wound care workstream has progressed from Red to Amber through collaboration with the wound care community provider network. A verbal update was provided for the long acting antipsychotic injections in schizophrenia workstream.

The Committee noted the workplan update.

8. Re-presentation of steroid emergency card guidance and patient information leaflet (PIL) for primary care

The Borough lead re-presented this item, which was previously presented at the October 2022 IMOC meeting; updates to the guidance and PIL were requested in line with the discussion in October 2022 as well as sharing the documents with the respiratory subgroup for review. An IMOC GP member also provided an additional review of the documents to assist with their refinement. The updates to the steroid emergency card guidance and PIL were outlined to Committee members in line with the summary of changes provided in the agenda pack. Minor comments were raised regarding grammatical and formatting updates to the guidance and PIL. The presenter confirmed that on-going review of the guideline and PIL will be under the responsibility of the lead Borough and the SEL ICS Medicines Safety Network.

Committee members approved the steroid emergency card guidance and patient information leaflet by consensus, pending updates to the guidance and PIL in line with the discussion.

ACTION: Author to update to the steroid emergency card guidance and patient information leaflet in line with discussion and progress for IMOC Chair's ratification

9. Re-presentation of recategorisation request for GLP-1 analogues from Amber 3 to Amber 2

The authors were in attendance to re-present this item which was presented at the November 2022 meeting. Committee members were requested to review the decision approved at the November 2022 meeting to re-categorise GLP-1 analogues from Amber 3 to Amber 2 with two months' supply from the specialist diabetes team to Amber 2 with one month supply as this would better support the capacity of the specialist diabetes teams. Committee members noted that the arrangements for the prescribing of GLP-1 analogues varies across SEL. In line with this, Committee members agreed the GLP-1 pathway, information sheet and fact sheet should be updated with a clear definition for "diabetes specialist" which enables initiation in primary care via appropriately trained diabetes specialist practitioners under the Amber 2 re-categorisation.

Committee members approved the recategorisation request for GLP-1 analogues from Amber 3 to Amber 2 with a minimum of one month supply from a diabetes specialist by consensus pending an update to the GLP-1 pathway, information sheet and factsheet in line with the discussion. The existing formulary recommendations will also be updated to reflect these amendments.

ACTION: GLP-1 pathway, information sheet and factsheet to be updated in line with the discussion
ACTION: Existing GLP1 related formulary recommendations to be updated to reflect the Amber 2 category and a minimum of one month's supply

10. Flash Glucose Sensor and Continuous Glucose Monitoring (CGM) guidance – planning and costings

A member of the Diabetes sub-group was in attendance to provide an update on the plans for SEL. The presenter's conflict of interest was noted by the Committee. NICE guidelines on the management of Type 1 diabetes (T1DM), Type 2 diabetes (T2DM) and children and young people (CYP) with diabetes were recently updated and have had a significant changes in recommendations made on the prescribing of Flash Glucose Sensor and Continuous Glucose Monitoring (CGM) devices. In line with this, the London Diabetes Network and London Procurement Partnership have developed regional guidance to support implementation of updated NICE guidance, which will be used to inform SEL local guidance.

In line with the regional T1DM Flash and CGM guidance, Committee members noted the device costings associated with implementing Flash and CGM guidance in T1DM in adults. As the approximate costings exceed the financial threshold the Committee is permitted to approve, this will need to be progressed to the Planning and Finance Committee for financial approval.

Formulary inclusion requests for the new CGM devices that are available on FP10 and a draft T1DM Flash and CGM guidance will be presented at a future IMOC meeting for approval.

11. Insulin degludec (Tresiba™) for the management of Type 1 diabetes and Type 2 diabetes in adult patients

This formulary submission originates from the KCH endocrinology team and is supported by GSTT and LGT. The application requests an extension to the existing formulary recommendation for the use of insulin degludec (Tresiba™) for T1DM adult patients where psychosocial factors, or requirement for third party administration mean a flexible timing of dose is important. The application also requests use in T2DM adult patients (new cohort) under the same criteria and enables alignment to the formulary recommendation for the use of Tresiba™ in children and young people over 12 years old with T1DM and T2DM.

- **Evidence review**

The Formulary Pharmacist presented an overview of the efficacy evidence for the extended use of insulin degludec (Tresiba™) for the management of T1DM and T2DM adult patients, the detailed evidence review was provided within the meeting agenda pack. The information presented also included the estimated resource impact for insulin degludec (Tresiba™). The resource impact of the submission is within the financial threshold that the Committee is authorised to approve.

- **Applicant's presentation**

The applicant was in attendance to present the submission and field any questions. The applicant's DoI was noted. The applicant clarified that the formulary application formalises the current local practice for the use of Tresiba™ where good experience has been observed in this setting and the use of Tresiba™ in T1DM and T2DM adults. The formulary application also requests a recategorisation change from Amber 3 to Amber 2 which would be aligned to the recently updated formulary recommendation for the use of Tresiba™ for the management of T1DM and T2DM in paediatrics.

The applicant clarified that the use of insulin degludec (Tresiba™) is unlikely to have an impact on the local implementation of biosimilar insulin as insulin degludec (Tresiba™) will not be used as first line insulin treatment in majority of patients in this setting. However in certain patient cohorts based on patient factors, insulin degludec (Tresiba™) may be the best first line insulin choice, although generally insulin detemir would be used first line, followed by insulin glargine followed by insulin degludec (Tresiba™).

Comments were raised regarding outcome data in relation to medicines value from the use of insulin degludec (Tresiba™) in this setting across SEL and that it would be useful for outcome data to be presented back to the Committee in 12 months e.g. the impact on hospital admissions.

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

Committee members discussed the application and members acknowledged the benefit of Tresiba™ in this setting and the importance of aligning the use of insulin degludec (Tresiba™) in adult patients with T1DM and T2DM with the local formulary recommendation for the use of insulin degludec (Tresiba™) in paediatrics. The Committee agreed by consensus the extended use of insulin degludec (Tresiba™) for the management of T1DM and T2DM adult patients and a recategorisation from Amber 3 (initiation and first 3 months supplied by the specialist diabetes team) to Amber 2 (initiation and first prescription from the specialist diabetes team).

ACTION: Existing formulary recommendation to be updated and presented at next meeting

12. Proposal for the use of oral isotretinoin in patients with moderate to severe acne prescribed by the Community Dermatology Services

A member of the SEL Dermatology Network and clinicians within the local Community Dermatology Service (CDS) were in attendance to present this proposal along with the borough lead. The proposal supports better patient access to isotretinoin for the management of moderate to severe acne. In SEL, all prescribing and dispensing of isotretinoin is within secondary care in line with its Red (hospital only) categorisation and Medicines Healthcare products Regulatory Agency (MHRA) advice.

There is an extensive wait time currently for specialist dermatology review for access to isotretinoin treatment, in line with this, the prescribing of isotretinoin via the CDS and dispensing via Community Pharmacies could provide improved patient access to isotretinoin for the local population where the wait time for specialist dermatology review is considerably less.

The MHRA was contacted by the project leads regarding their views on the prescribing and dispensing of isotretinoin in primary care, the MHRA advised that the key principles are to ensure the CDS' prescribing oral isotretinoin are consultant-led and community pharmacists dispensing isotretinoin are following the pharmacist's checklist. The proposed arrangements for accessing isotretinoin via the CDS has been shared via the dermatology sub-group and ICS medicines safety network and updated in line with the comments received. The main concern associated with the prescribing and dispensing of isotretinoin in the community is ensuring the pregnancy prevention programme (PPP) is followed.

Comments were raised regarding further engagement with the Local Pharmaceutical Committee (LPC), the community pharmacy expressions of interest process, as well as the importance of agreeing how the funding for prescribing and dispensing isotretinoin via the CDS will be moved to primary care prescribing budgets/potentially fund a community pharmacy service. Committee members also noted that the MHRA and Commission on Human Medicines (CHM) are currently reviewing the current recommendations for isotretinoin treatment, it is important any changes in practice which may arise following the review are implemented in a timely way.

Committee members agreed by consensus that the approval of the proposal to develop a service which enables the prescribing and dispensing of isotretinoin for the management of moderate to severe acne via the SEL CDS is outside the remit of the Committee to approve. However, the Committee is able to consider the clinical, medicines aspects of the service i.e. the clinical guideline which will be used by the service however additional actions are required before the Committee can approve the supporting clinical guideline.

- **Comments raised by Committee members to be taken forward by the presenters and the borough leads.**
- **Governance and safety elements of the service to be reviewed and be made clearer and approved by the SEL ICS Medicines Safety Network or alternative identified processes and presented to the SEL IMOC for noting. Members agreed that governance is crucial and community pharmacists should be clear regarding what is expected of them.**
- **The clinical guideline to be shared with the dermatology sub-group for consultation prior to SEL IMOC approval.**

ACTION: The updated oral isotretinoin in patients with moderate to severe acne prescribed by the Community Dermatology Services clinical guideline to be presented for approval at a future IMOC meeting.
ACTION: Dermatology leads and the borough leads to collectively follow up the comments raised and suggested next steps

12. Standing Items

- Formulary Submissions tracker

Noted

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

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

13. Any Other Business:
Committee members agreed a hybrid/face to face meeting can be organised for the March meeting.

IMOC dates for next 3 months

Date	Time	Venue
16th February 2023	2:00pm – 4:30pm	MS Teams
16th March 2023	2:00pm – 4:30pm	MS Teams
20th April 2023	2:00pm – 4:30pm	MS Teams