South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
17 November 2022 (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. 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 grammatical and 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 lipid management pathways

The author was in attendance to present the lipid pathways. The summary outlines the main changes made, which are also highlighted within the guidance.

Icosapent ethyl has been added to the pathway for use in line with NICE TA805. The CVD subgroup have recommended a RAGG categorisation of Amber 2 (specialist initiation) for icosapent ethyl. Committee members noted the estimated local resource impact for icosapent ethyl provided within the agenda pack, which includes estimates based on both NICE and local estimates. As the upper figure exceeds the financial thresholds the Committee is permitted to approve, this will need to be progressed to the Planning and Finance Committee for financial approval.

The use of bempedoic acid with ezetimibe in line with NICE TA 694 is locally approved as Amber 2 (specialist initiation). As the use of bempedoic acid locally is better established, the Committee was requested to consider a recategorisation of bempedoic acid with ezetimibe to Amber 1 (initiation in primary care on the recommendation of a specialist). In addition to this, the Committee was requested to consider the formulary inclusion of bempedoic acid monotherapy as Amber 2 (specialist initiation) for patients where statins and ezetimibe are contraindicated or not tolerated, and bempedoic acid monotherapy may be beneficial. Use as monotherapy is not covered by NICE TA 694 but is in line with the product licence.

A comment was raised regarding the development of a one page summary guide separate from the main lipid pathway with key messages for the management of primary and secondary prevention of CVD which would be more useful and easier to access for primary care colleagues and this could link to the detailed pathways. Additional comments in relation to the lipid pathways included the addition of the cohorts of patients eligible for switching from a PCSK9i to inclisiran in line with NICE to be better described and the inclusion of shared decision making and overprescribing/deprescribing elements in relation to lipid therapies. Members discussed whether there is a clinical need for bempedoic acid monotherapy if this has not been reviewed by NICE. The author responded that it's unlikely that NICE considered monotherapy i.e it is not covered given the small patient cohort however, bempedoic acid monotherapy is licensed in this setting and would be useful to trial.

Committee members approved the lipid pathways by consensus pending the amendments discussed and presentation to the Planning and Finance Committee of the icosapent ethyl costings. At this stage the pathways have been clinically signed off (pending amendments) but will not be published until financial sign off is completed.

Committee members agreed by consensus the formulary inclusion of bempedoic acid monotherapy in patients with a contraindication or intolerance to ezetimibe and statins as Amber 2 (specialist initiation). Members also agreed that all indications of bempedoic acid should have the same RAGG categorisation to avoid confusion in primary care, in line with this Committee members agreed bempedoic acid with ezetimibe should remain as Amber 2 (specialist initiation). Committee members also agreed by consensus an Amber 2 (specialist initiation) categorisation for icosapent ethyl.

ACTION: Development of a one page summary guide with key messages for the management of primary and secondary prevention of CVD in primary care
ACTION: Estimated local resource impact for icosapent ethyl to be updated with Bromley borough data and progressed to the Planning and Finance Committee
ACTION: Lipid pathway to be updated in line with discussions and ratified via Chair's action upon financial approval of icosapent ethyl from the Planning and Finance Committee

5. Formulary recategorisation of acamprosate and naltrexone in alcohol dependence from Amber 3 to Amber 2

The applicants, both specialists in addictions, were in attendance to present this item. In line with NICE guidance, acamprosate and naltrexone are recommended as first line relapse prevention treatment in alcohol dependence. The request being made to the Committee is for acamprosate and naltrexone in alcohol dependence to be categorised as Amber 2 (specialist initiation).

Across SEL the continuation of acamprosate and naltrexone in primary care following initiation by a hospital specialist varies across the six boroughs and is limited due to the Amber 3 (shared care) categorisation on the joint SEL formulary, which is not a true reflection of how acamprosate and naltrexone are managed in primary care. In primary and community care, the provision of acamprosate and naltrexone is commissioned through the individual six Local Authorities (LA) in SEL. It was suggested that in the interim it would be more accurate if there is no RAGG category for acamprosate and naltrexone on the local joint formulary and a note is added that the relevant borough Medicines Optimisation team should be contacted to confirm what the arrangements are for the community drug and alcohol services in that borough.

Members discussed the patient cohort who require treatment with acamprosate and naltrexone who are often complex and benefit from continuity of care i.e. review and prescribing via the community drug and alcohol services, who currently provide this service in majority of the SEL boroughs. The provision of the accompanying psychosocial care was also discussed, in particular what mechanisms would be in place to support primary care to ensure this occurs. If prescribing is to occur by primary care clinicians, it is important training and education is also provided. The presenters clarified that patients seen within the acute and mental health trusts are usually the group of patients who will not attend the LA commissioned service, so there is a gap in their care provision in primary care. This patient cohort is quite stable and tend to have good compliance with their treatment if they are regulary seen by the specialist teams. Education and training can also be provided to better support clinicians in primary care.

Members noted that specific follow up may vary across the SEL Trusts and the recategorisation will need to take into account the process for each Trust. In line with this clarity is needed on how the process of initiating acamprosate and naltrexone via the acute non-psychiatric Trust and mental health Trusts in SEL and appropriate follow up in primary care will occur.

Committee members agreed by consensus that a decision on the RAGG recategorisation could not be ratified at the meeting and further views from the six LAs on the proposed recategorisation for acamprosate and naltrexone is required via the Borough Medicines Leads. A detailed proposal is also required which provides a framework on how acute and mental health Trusts will initiate acamprosate and naltrexone, provide follow up post initiation and support primary care with continual prescribing and monitoring. The applicants were also requested to consider what training will be provided to primary care.

ACTION: Borough Medicines lead representatives to discuss views on the recategorisation of acamprosate and naltrexone from Amber 3 to Amber 2 with their local authority commissioners of the community drug and alcohol services
ACTION: Proposal on the prescribing arrangements for acamprosate and naltrexone from acute and mental health Trusts to primary care as an Amber 2 medication to be updated with the further information discussed for presentation at a future meeting

6. Anti-epileptic drug (AED) pathway review - survey results and next steps

The formulary pharmacist presented this item alongside the specialist neurosciences Pharmacist who was in attendance and the Borough lead for epilepsy. This follows discussion at a previous meeting on the approach to be taken to the review of the existing AED treatment pathway. As a result of previous discussions, a survey was sent out to primary care clinicians to better understand the current usage of the pathway and understand what is needed in primary care to support the safe and appropriate prescribing of AEDs.

The survey was circulated to primary care over two weeks in July 2022, there are around 200 practices in SEL and responses were received from 25 GPs, 4 pharmacist prescribers and one "other" respondent. Recommendations following a review of the survey results include:

- A series of webinars should be provided by the KCH specialist neurology team for primary care clincians to increase knowledge and confidence in the prescribing and monitoring of AEDs
- Inclusion of RAGG categorisaion, MHRA alerts and prescribing support for AEDs to the joint medicines formulary
- Improvement to clinical letter templates and addition of electronic links to useful resources such as NICE guidance
- Retirement of the existing AED pathway due to the poor awareness and use of the pathway

Members discussed the survey results and recommendations and as the survery was sent out for a short period and had a low response rate, members questioned whether it would be valid to withdraw the pathway rather than updating it. It was noted that the AED pathway sets out where these medicines fit in terms of use and the pathway is a good educational tool for primary care, including pharmacist and nurse prescribers and whether it would be possible to increase the awareness of the pathway at borough level as well as the education webinars and re-survey in a year. The presenters clarified that the AED pathway is no longer fit for purpose and is more of a risk than a benefit to clinicians as the NICE guidance has significantly changed since the development of the AED pathway. The NICE guidance is up to date and would be of better benefit to local primary care clincians. A comment was also raised that a new abridged version of the AED pathway may be useful so that primary care clinicians understand what steps to take to manage epilepsy in primary care, when to refer, and how to review patients and their medication

Committee members agreed by consensus that the AED pathway should be retired, instead the NICE epilepsies diagnosis and management guidance should be promoted to primary care and the formulary should make clear the place in therapy of the various agents. The education and training webinars by the KCH specialist neurology team should be held quarterly at varying times and dates and a timetable plan for the webinars should be provided at the next IMOC meeting and the detailed template clinic letter at the January IMOC meeting.

ACTION: AED education and training webinar timetable plan to be provided at the next IMOC meeting.
ACTION: Enhanced AED template clinic letter to be developed and shared at the January 2023 IMOC meeting.
ACTION: Development of a shorter guide to be considered by the authors, supported by the lead borough.

7. Rituximab (Rixathon™) injection for the treatment of autoimmune haemolytic anaemia

This formulary submission originates from a haematology consultant at KCH and is supported by GSTT and LGT. The application requests the use of rituximab (Rixathon™) 375mg/m^2 or 100mg/m^2 injection for the management of autoimmune haemolytic anaemia (AIHA) as a single course of 4 doses over 4 weeks.

➢ Application and evidence review

The Formulary Pharmacist presented an overview of the efficacy evidence for the use of rituximab off-label in this setting, the detailed evidence review was provided within the meeting agenda pack. The information presented also included the estimated resource impact for rituximab, the resource impact of

the submission is within the financial threshold that the Committee is authorised to approve. The resource impact is based on the use of the best value rituximab product (currently the biosimilar). It is expected that the introduction of rituximab could potentially offset costs of reduced transfusion requirements for this patient cohort and a reduction in the volume of individual funding requests being submitted.

- **Applicant's presentation**

The applicant was in attendance to present the submission and field any questions. The applicant's DoI was noted. The applicant confirmed that rituximab will be used as a single course in this setting and used as second line treatment in all types of AIHA expect from cold haemagglutinin disease (CHAD) where rituximab is recommended as a first line option and first line alongside steroid treatment for patient with severe or atypical forms of AIHA.

A comment was raised regarding the evidence available for the use of rituximab at the lower dose of 100mg/m^2 which is limited and if rituximab is approved for the use at the standard dosing (375mg/m^2), would this be acceptable for use in this patient cohort. The applicant clarified the use of rituximab in this setting at standard dosing would be acceptable as this dose is used in majority of cases, however the lower dose was included in the application as there are some patients already initiated on this dose and it would be useful to continue this dose in such patients.

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

Committee members discussed the application and members acknowledged that rituximab (Rixathon™) injection 375mg/m^2 as a single course of 4 doses over 4 weeks is suitable as second line treatment of all types of AIHA except where it can be used as first line treatment for the management of severe/atypical forms of AIHA and CHAD. The Committee agreed by consensus a category of Red (hospital only).

ACTION: Formulary recommendation to be drafted and presented at next meeting

8. Updated rheumatology treatment pathways

The author was in attendance and presented the updated rheumatoid arthritis (RA) and seronegative spondyloarthropathies (SpA) pathways and cost tools. The RA pathway has been updated with minor changes including the addition of supporting information for the prescribing of subcutaneous (S/C) infliximab and the addition of S/C infliximab to the cost tool.

The SpA pathway has been updated in line with the new NICE TAs for the use of upadacitinib for ankylosing spondylitis and risankizumab for psoriatic arthritis (PsA) as a second line option. The SpA pathway has also been updated to include the use of guselkumab in line with the updated NICE TA which has been expanded to enable the first line use of guselkumab in PsA patients with contraindications to an anti-TNF alpha. The SpA cost tool has been updated to include upadacitinib and risankizumab.

Committee members approved the RA and SpA pathway and cost tool by consensus.

9. Updated glucagon-like peptide (GLP-1) analogue documents for adults aged 18 years and over with Type 2 Diabetes Mellitus (T2DM) and formulary requests

Members of the diabetes sub group were in attendance to present this item which includes the request for the:

- Formulary inclusion of the higher strength dulaglutide (Trulicity™) 3mg and 4.5mg formulations for the management of T2DM
- Formulary recategorisation of GLP1- analogues from Amber 3 to Amber 1

The formulary inclusion request for dulaglutide 3mg and 4.5mg is being made as the higher strengths were not available when the lower strength preparations were added to formulary and they provide additional benefit to the management of HbA1c and weight reduction in T2DM.

Committee members noted that during the COVID-19 pandemic, GLP-1 analogues were recategorised from Amber 3 (shared care) to Amber 2 (specialist initiation) on an interim basis to enable continual initiation of GLP-1 analogues. Through the recategorisation of GLP-1 analogues from Amber 3 to

Amber 2, further expertise in the prescribing of GLP-1s has been built through experience and training in primary care. In line with this the diabetes subgroup recommend a recategorisation of GLP-analgoues to Amber 1 (initiation in primary care on the recommendation of a specialist).

The GLP-1 pathway, information sheet and safe prescribing information sheet have been updated to reflect the formulary inclusion request for dulaglutide 3mg and 4.5mg and RAGG recategorisation request of Amber 1 for GLP-1 analogues and are also being presented for approval.

A comment was raised as to whether the recommendation in the paperwork for the removal of the various formulary recommendations for GLP-1 agents be reviewed and an update to the formulary recommendation be considered instead. The authors confirmed the formulary recommendations can remain and be updated in line with the approvals.

Members agreed that an Amber 2 categorisation for GLP-1s would be preferable. The presenters noted that under the current provision of GLP-1 analogues as interim Amber 2, the specialist team provide 3 months supply and queried if this could this be reduced to 1 month supply. Members debated this and in line with the views that current practice for outpatient medication is usually one month supply or less, an agreement of Amber 2 with one month supply from the specialist was agreed.

After the presenters left the meeting, further discussions occurred in regards to the consensus view from some primary care Committee members that an Amber 2 categorisation with two month supply was more appropriate for the use of GLP-1 analogues in this setting. Some members felt there may be risk of patients experiencing a gap in their GLP-1 provision if one month supply is provided by the specialist due to the access issues in primary care. It was noted however, there are other medicines under Amber 2 for which a one month supply of medication is provided, including a number of long acting insulins. Following further discussion, it was agreed that a 2-month supply of GLP-1 analogues from the specialist would be trialled for six months to understand if there are issues with patients receiving the medication in a safe and timely way.

Committee members agreed by consensus the formulary inclusion of dulaglutide 3mg and 4.5mg and the formal recategorisation of GLP-1 analogues as Amber 2 with two month supply from the specialist diabetes team. Feedback was requested to be provided back to the Committee in 6 months on the transfer of prescribing process for a review with a view to reduce the GLP-1 two month supply from the the diabetes specialist team to one month supply if no issues were experienced in primary care.

ACTION: Dulaglutide (Trulicity™) 3mg and 4.5mg solution for injection to be added to the SEL JMF for the management of T2DM
ACTION: Existing GLP-1 formulary recommendations (for dulaglutide, injectable semaglutide and oral semaglutide) to be updated and presented at a future IMOC meeting
ACTION: SEL JMF, GLP-1 pathway and GLP-1 information sheet to be updated with GLP-1 analogue recategorisation to Amber 2 (specialist initation and prescribing for a minimum of 2 months)
ACTION: Feedback to be provided back to the Committee in 6 months on the transfer of prescribing process for GLP-1 analogues as an Amber 2 medication with 2 month supply

10. Use of nystatin to treat early voice prosthesis failure due to candida – information for primary care

The formulary pharmacist presented this item, which has been developed as part of the formulary application for the use of nystatin to treat early voice prosthesis failure due to candida. The application was considered by the Committee in September 2021 and was was approved as Amber 1 (initiation in primary care on the recommendation of a specialist) pending development of information for primary care. A minor amendment was requested with respect to the quantities to be prescribed in primary care. Committee members agreed by consensus the GP information sheet for the use of of nystatin to treat early voice prosthesis failure due to candida pending updates in line with the discussion.

ACTION: GP information sheet to be updated and ratified via Chair's action
ACTION: Formulary recommendation to be drafted and presented at next meeting

11. Standing Items

- Formulary Submissions tracker

Noted.

- NICE Technology Appraisal Guidance Summary – ICS and NHS England attributed medicines
  - The summary was noted and RAGG categories were agreed by consensus.
  - Members agreed by consensus an update to the local formulary entry noting that the locally agreed Red categorsation for SQ HDM SLIT for treating allergic rhinitis and allergic asthma caused by house dust mites pre-dates the NICE terminated appraisal (TA834)

ACTION: Formulary website to be updated to make clear that SQ HDM SLIT formulary inclusion pre-dates NICE terminated appraisal.

- RMOC Update - the Committee noted an update from the November RMOC meeting
- Committee members noted the updated wording to the formulary highlighting that vitamin B compound strong tablets should not be used for the prevention of Wernicke's Encephalopathy in alcoholism in line with national guidance from the RMOC.

12. Any Other Business:

Committee members were informed that this was the last meeting for the formulary support pharmacist and thanked them for their support during their time with the Committee.

IMOC dates for next 3 months

Date	Time	Venue
15th December 2022	2:00pm – 4:30pm	MS Teams
19th January 2023	2:00pm – 4:30pm	MS Teams
16th February 2023	2:00pm – 4:30pm	MS Teams