South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
Thursday 16th November 2023 (Meeting held via MS Teams)
FINAL Minutes

1. **Welcome, introductions and apologies**
   The Chair welcomed attendees to the meeting. Apologies, new members 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 notes and minutes were accepted as an accurate record of the meeting subject to the correction of minor typographical errors and an update to the wording on the annual local estimate at steady state (year 5) for the use of upadacitinib in ulcerative colitis.

4. **Clinical Effectiveness South East London (CESEL) atrial fibrillation (AF) guide**

   The authors were in attendance to present this item, which aims to support primary care clinicians across SEL with the diagnosis and management of atrial fibrillation (AF) as well as stroke prevention in this setting and includes information on prescribing anticoagulants. The guide will be tailored to each Borough due to the differences such as access to diagnostics. The medicines content will remain consistent across the six SEL boroughs.

   A comment was raised in relation to the Red, Amber, Green, Grey (RAGG) category for direct oral anticoagulants (DOAC) which is Amber 2; this should be reflected within the guide. A caveat should also be added that DOACs in AF can be initiated in primary care by suitably competent and qualified practitioners in line with local arrangements. A comment was also raised regarding updating the guide to note the licensing and NICE approval for DOACs in this setting covers non-valvular AF and the inclusion of a prescribing resources section, with links to SEL IMOC guidance and resources for the use of DOACs in AF.

   Committee members approved the CESEL AF guide by consensus pending amendments to the guide in line with the discussions.

   ACTION: Guideline to be updated by authors and progressed for ratification via Chair's action

5. **SEL AF and venous thromboembolism (VTE) direct oral anticoagulant (DOAC) guidance & resources update**

   The author was in attendance to present this item which has been reviewed and updated via the cardiovascular disease (CVD) sub-group of the IMOC. Main updates to the documents include the clarification that a transfer of care document is no longer needed following DOAC initiation by a specialist in line with Amber 2 categorisation and the preferred DOAC for the management of stroke prevention in AF (edoxaban) and VTE treatment (rivaroxaban) in line with national recommendations.

   An update was requested to the DOAC frequently asked questions (FAQ) to note that the first line proton pump inhibitor for patients on clopidogrel is pantoprazole. General formatting comments were also raised. The antidote FAQ should make clear that that the DOAC antidotes (idarucizumab and andexanet alpha), are hospital only medications.

   Committee members approved the AF and VTE DOAC guidance and resources by consensus pending minor amendments in line with the discussion.

   ACTION: Guideline and resources to be updated by author and progressed for ratification via Chair's action

6. Bempedoic acid frequently asked questions (FAQ)

The author was in attendance to present this item following the recategorisation of bempedoic acid/ezetimibe combination from Amber 2 to Green and bempedoic acid monotherapy from Amber 2 to Amber 1. The FAQ has been developed via the CVD sub-group of the IMOC to support primary care clinicians prescribe and manage the use of bempedoic acid in this setting.

A comment was raised in relation to clarifying that bempedoic acid has a Green RAGG specifically for the bempedoic acid/ezetimibe combination.

Committee members approved the bempedoic FAQ by consensus pending the minor amendment in line with the discussion.

ACTION: Bempedoic acid FAQ to be updated and progressed for ratification via Chair's action

7. SEL Acute Provider Collaborative (APC) Gynaecology Network primary care menopause guideline and associated formulary requests

Colleagues from the SEL APC were in attendance to present this item. The menopause guideline is the first guideline developed via the network and will form part of a full suite of guidelines for the management of gynaecology conditions. The guideline aims to standardise and improve the available information and education to support the management of menopause in primary and secondary care. The guidance includes information on hormone replacement therapy (HRT) choices in menopause, management of post-menopausal bleeding whilst on HRT and lifestyle recommendations.

The guidelines were circulated for consultation with the IMOC and for broader consultation to all GP practices in SEL, the Local Medical Committee (LMC) and the SEL Cancer network.

Alongside the approval of the medicines section of the guideline, Committee members were also requested to consider the approval of the following formulary inclusions:

- Medroxyprogesterone 5mg & 10mg for progestogenic opposition of oestrogen HRT as Green (off-label)
- Elleste Duet™ 1mg & 2mg tablets for HRT as Green
- Indivina™ 1mg/2.5mg, 1mg/5mg & 2mg/5mg for HRT as Green
- Blissel™ 50 micrograms/g vaginal gel for vaginal atrophy as Green
- Tostran™ gel and Testogel™ for decreased libido in menopausal women (off-label) recategorised from Amber 2 (specialist initiation) to Amber 1 (initiation in primary care in with specialist recommendation) and inclusion of Testim™ 1% gel as Amber 1
- Green categorisation of tibolone 2.5mg tablets for the treatment of oestrogen deficiency symptoms in postmenopausal women

A comment was raised regarding the formulary requests for Elleste Duet™, Indivina™ and whether their use is intended as treatment options or to support shortages as noted within the formulary applications. The presenter clarified Elleste Duet™ and Indivina™ are HRT treatment options and use will be based on patient factors and preference and medroxyprogesterone is a third line progesterone HRT treatment option. This will be clarified within the guideline.

A comment was raised in relation to the recommendations associated with increasing HRT in women on combined transdermal patches and whether this will be within the licensed dose. The presenter clarified the increased dose should be within the licensed dosing range, for Evorel™ Conti patch the guideline will be clarified to state the starting dose is 50 micrograms, meaning any dose increase would result in a maximum dose of 100 micrograms as per the licence. Clarification was also sought regarding the use of norethisterone 5mg for 14 days per cycle and if this will be used as add on treatment. The presenter explained norethisterone is a treatment option as a progesterone HRT component and the dosing, which is different to the British National Formulary (BNF) is in line with expert opinion which will be noted explicitly within the guideline.

In relation to the formulary inclusion request for Testim™, a query was raised regarding whether Testim™ is an additional second line option to Tostran™. The presenter clarified Testim ™ is a second line option after Tostran™ alongside Testogel™ which is also a second line option and will be made clearer within the guideline.

Committee members approved the following by consensus:

- The medicines section of the SEL APC gynaecology network primary care menopause guideline pending updates to the guideline in line with the discussion followed by approval via IMOC Chair's ratification
- Formulary inclusion of:
  - Medroxyprogesterone as Green for the progestogenic opposition of oestrogen HRT (off-label) as a 3rd line option.
  - Elleste Duet™ 1mg & 2mg tablets as Green in line with licensed indication
  - Indivina™ 1mg/2.5mg, 1mg/5mg & 2mg/5mg tablets as Green in line with licensed indication
  - Blissel™ 50 micrograms/g vaginal gel as Green as per licensed indication
  - Testim™ gel as Amber 1 for decreased libido in menopausal women (off-label) – 2nd line testosterone gel option alongside Testogel™.
  - Tostran™ and Testogel™ recategorisation from Amber 2 to Amber 1 for decreased libido in menopausal women (off-label)
  - Tibolone categorised as Green in line with licensed indication

ACTION: Guideline to be updated and progressed for ratification via Chair's action
ACTION: Addition of medroxyprogesterone, Elleste Duet™, Indivina™, Testim™ to the SEL JMF in line with the agreed RAGG categories and place in therapy
ACTION: Recategorisation of Tostran™ and Testogel™ from Amber 2 to Amber 1 in the SEL JMF
ACTION: Tibolone to be categorised as Green in the SEL JMF

8. Rivaroxaban for post deep vein arterialisation with posterior tibial vein stenting in patients with peripheral arterial disease

This formulary submission originates from a Consultant of Vascular Surgery at GSTT. The application requests the use of rivaroxaban 20mg (1 year to lifelong treatment) for post deep vein arterialisation (DVA) with posterior tibial vein (PTV) stenting in patients with peripheral arterial disease (PAD) to maintain long term patency of tibial vein stents and minimise possible long-term thrombosis and reintervention. This use of rivaroxaban in this setting is off- label and will be limited to GSTT who are a tertiary centre for this procedure.

- **Evidence review**

The Formulary Pharmacist provided an overview of the efficacy evidence for the use of rivaroxaban in this setting. A detailed evidence review was provided within the meeting agenda pack. The information presented also included the estimated resource impact for rivaroxaban in this setting. The resource impact of the submission is within the financial threshold that the Committee is authorised to approve.

- **Applicant's presentation**

The applicants were in attendance to present the submission and field any questions. The applicant's declaration of interest was noted. The applicants clarified that DVA with PTV stenting in patients with PAD is a new process which has shown to have benefit in the management of CLTBI. Post procedure anticoagulation with rivaroxaban has become consensus at GSTT in this setting and is one of the largest centres nationally for DVA as well as other centres worldwide. At GSTT there are currently 13 patients who have been treated with rivaroxaban in this setting and all patients have experienced good results including maintaining primary patency of the stents to date.

Patients will be discharged with a minimum of 3-month supply and patients will be regularly reviewed at 3, 6, 9 and 12 months; at 12 months a decision will be made to continue rivaroxaban or switch to dual platelet therapy (DAPT). As GSTT is a tertiary centre for this procedure, there will be some patients who are not local residents and in these instances the team would like to request GPs to

continue the prescribing of rivaroxaban.

A comment was raised regarding whether all patients will receive rivaroxaban treatment for 12 months and then transferred to DAPT with a request for primary care to continue prescribing or if some patients will remain on rivaroxaban after 12 months, and if so, is there a specific cohort of patients who fall into this category. The presenter clarified 12 months of treatment with rivaroxaban followed by DAPT is the standard treatment if a patient's LimFlow System remains patent throughout the 12 months. The prescribing of rivaroxaban will remain with the specialist for the 12 months of treatment. Prescribing in primary care will be requested for the very few patients (1 - 2 patients) who may need treatment with rivaroxaban beyond 12 months. The presenter also shared, for the 13 patients who have been initiated on rivaroxaban, no patients have required treatment beyond 12 months at present.

In line with the limited evidence for the use of rivaroxaban in this setting, especially at treatment dose which is off label; GP Committee members shared that all prescribing would be safer and appropriate in secondary care (Red RAGG category).

A comment was also raised in relation to any papers being published soon which will provide evidence in relation to the optimal anticoagulation regime in this patient cohort. The presenter explained the team are unaware of this currently and information from industry partners does not suggest this is in the pipeline.

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

Committee members discussed the application and members acknowledged that whilst there are insufficient data in the literature, there is expert consensus that rivaroxaban is appropriate antithrombotic option post DVA with PTV stenting in patients with PAD. However, concern was raised by some GP members regarding the continuation of rivaroxaban post 12 months being transferred to primary care due to the off-label indication and lack of evidence for use of rivaroxaban in this setting. Additionally, expected patient numbers are low. It was noted that a RAGG category of red does allow requests to primary care to be made if the specialist feels there are exceptional circumstances for a request to be made. This should be discussed and agreed on a case-by-case basis with the primary care clinician.

Committee members agreed a RAGG category of Red (hospital only) by consensus. Further discussions will take place outside of the meeting for clarity on the specific criteria under which patients would require treatment beyond 12 months.

ACTION: Formulary recommendation to be drafted and presented at a future meeting

9. **Formulary inclusion of azithromycin 15mg/g single use preservative free eye drops (Azyter™) as Amber 2 for the management of:**
    - **Trachomatous conjunctivitis (licensed in children (aged from birth to 17 years) and adults)**
    - **Purulent bacterial conjunctivitis (licensed in children (aged from birth to 17 years) and adults). Restricted to use where chloramphenicol is not appropriate, especially where gram negative infection suspected.**
    - **Anterior/posterior blepharitis (off-label)**

The applicant was in attendance to present this request. Azithromycin 15mg/g single use preservative free eye drops (Azyter™) is licensed as first line treatment for trachomatous conjunctivitis and second line treatment of purulent bacterial conjunctivitis in children and adults. Azyter™ is included in the pan-London ophthalmology formulary and categorised as Amber – no tiers are presented for the amber RAGG category in the pan-London ophthalmology formulary.
Committee members were requested to consider the formulary inclusion of Azyter™ in line with the licensed indications as well as the off-label indication of anterior/posterior blepharitis where chloramphenicol is contraindicated (second line treatment). The formulary pharmacist provided a brief overview of the detailed evidence review provided within the meeting agenda pack. The information presented also included the estimated resource impact for Azyter™ in this setting.

The resource impact of the submission is within the financial threshold that the Committee is authorised to approve.

Members requested clarity on the RAGG category being sought for the different indications. It was noted that in the licensed indications of trachomatous conjunctivitis and purulent bacterial conjunctivitis, the treatment course is only for 3 days. The applicant confirmed that the intention is for these licensed indications to be categorised as Red as the full course will be from the hospital. However, for the off-label indication of blepharitis, the desired RAGG category is Amber 2 (specialist initiation, then continuation in primary care).

A comment was raised regarding the management of blepharitis and the place in therapy for azithromycin. The applicant clarified initial treatment is with topical lubricants alongside hygiene measures. If this is ineffective, a steroid eye drop or a steroid sparing eye drop such as ciclosporin is used. Azithromycin would be a treatment option as an alternative to ciclosporin eye drops which is more expensive and requires regular review by a specialist. Topical azithromycin is also a preferred option in comparison to repeat prescriptions for oral antibiotics. In response to a query on the number of cycles of treatment needed for blepharitis, the applicant explained effectiveness is usually seen within two weeks of treatment, however it is difficult to predict how many repeat courses a patient will require.

The Committee approved by consensus the formulary inclusion of azithromycin 15mg/g single use preservative free eye drops (Azyter™) for the management of anterior/posterior blepharitis (off-label) as Amber 2 (specialist initiation) with the complete first cycle prescribed by the specialist. The formulary will need to be clear that the first cycle is to be prescribed by the hospital. The Committee also approved formulary inclusion under a RAGG category of red (hospital only) for the licensed indications of trachomatous conjunctivitis and purulent bacterial conjunctivitis.

ACTION: Azithromycin 15mg/g single use preservative free eye drops (Azyter™) to be added to SEL JMF as Amber 2 for anterior/posterior blepharitis, with detail on the first cycle from the hospital. Also to be added as Red for the licensed indications

10. Formulary recommendations:

Updated recommendation 024 - Paliperidone palmitate (Xeplion™, Trevicta™ and Byannli™) depot injection for the treatment of schizophrenia in adults
This formulary recommendation has been updated following the approval of the updated paliperidone for the management of schizophrenia in adults shared care guideline to include the 6 monthly paliperidone preparation Byannli™ at the October IMOC meeting. Comments were received via the triage panel review and an updated version was shared on screen. There were no further comments from Committee members.

New formulary recommendation 147 - Colchicine for the secondary prevention of ischemic heart disease in adults
This formulary recommendation has been drafted following the time limited formulary application approval for colchicine in this setting under a Red RAGG category at the October IMOC meeting. This is a 12-month time limited approval to enable an outcomes report to be presented back to the committee in a years' time. A comment was received via the triage panel and the CVD sub-group lead which will be added post meeting.

Committee members approved both formulary recommendations by consensus pending minor amendments, as discussed, to formulary recommendation 147.

ACTION: Formulary recommendation 147 to be updated and progressed for ratification via Chair's action

11. Hydroxycarbamide for the treatment of sickle cell disease in paediatrics shared care guideline

The authors were in attendance to present this item which has been developed following approval for a shared care guideline to be progressed at the May 2023 IMOC meeting, to formalise the existing Amber 3 (shared care) categorisation for hydroxycarbamide in this setting. A comment was raised regarding how blood monitoring would be managed as patients will be reviewed by the specialist every 3 months and whether this would be carried out by the specialist team. The presenter clarified that the three-monthly review by the specialist team is via a CNS specialist nurse led clinic which is a telephone clinic. For patients who are local, blood monitoring can be done via the specialist, for patients who are not local residents it is easier for the GP to arrange blood monitoring in line with the shared care agreement and this can be clarified within the guideline.

Another comment was raised in relation to whether parents will be made aware that hydroxycarbamide is unlicensed in children under the age of 2 years old. The presenter explained all parents are counselled and provided with this information at the point of initiation, there is also a patient information leaflet which provides information on the benefits of hydroxycarbamide from the age of nine months

Committee members approved by consensus the hydroxycarbamide for the treatment of sickle cell disease in paediatrics shared care guideline pending updates in line with the discussion.

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

12. Standing items

- Formulary submissions tracker

Noted.

- NICE Technology Appraisal (TA) Guidance Summary ICS & NHSE/I attributed medicines:
  - The summary was noted, and RAGG categories were agreed by consensus.
- For information and noting:
- Paediatric formulary updates
- ApoGo™ vs Dacepton™ (apomorphine) product comparison
- Information to support primary care in managing patients affected by the shortages of methylphenidate prolonged-release capsules and tablets, lisdexamfetamine capsules, and guanfacine prolonged-release tablets - approved via the urgent Triage Panel process on 18th October 2023
- Information to support primary care in managing patients affected by the shortages of bumetanide 1mg and 5mg tablets - approved via the Triage panel process on 7th November 2023

These were noted by Committee members.

13. Any Other Business

Members were reminded that there is an additional, shorter IMOC meeting scheduled on 30th November. A reminder was also provided in relation to the December IMOC meeting which will be a hybrid meeting taking place in person and via MS Teams.

IMOC dates for next 3 months

Date	Time	Venue
14th December 2023	2:00pm – 4:30pm	Hybrid – MS Teams/in person
18th January 2024	2:00pm – 4:30pm	MS Teams
15th February 2024	2:00pm – 4:30pm	MS Teams