South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
18th September 2025 (Online via MS Teams)
Final Minutes

1. Welcome, introductions and apologies

The Chair welcomed attendees to the meeting. Apologies and observers were noted, and the meeting was confirmed to be quorate.

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.

3. Detailed action notes of the last meeting, minutes, 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. Members were provided with an update on the progress against actions due for this month, these were noted, and items closed were agreed.

4. i. SEL Medical Retinal Treatment Pathway in Wet Age-Related Macular Degeneration (wet AMD) and associated costings:

- **Wet AMD pathway**
- **Cost modelling for wet AMD**
- **Aflibercept 2mg biosimilar formulary request**
- **Formulary request and cost modelling for aflibercept 8mg**
- **Outcomes and monitoring framework 2025/26**

- **Wet AMD pathway and cost modelling**

The applicants were in attendance to present this item with support from members of the SEL Integrated Care Board (ICB) leads on behalf of the Medical Retinal Therapies sub-group. The SEL medical retinal treatment pathway for wet AMD has been adapted from NHS England's (NHSE) national treatment pathway and has been through IMOC consultation and approved via the ophthalmology medical retinal therapies sub-group. In line with NHSE's guidance, the pathway recommends the use of biosimilar preparations ranibizumab and aflibercept 2mg (once available) as the 1st line options for treating adults with wet AMD. Second line options are the longer acting anti-vascular endothelial growth factor therapies (anti-VEGF) agents aflibercept 8mg (preferred 2nd line choice) and faricimab. The main adaptations to the national wet AMD pathway in the SEL version include:

- Appendix 1 added – LogMAR and Snellen scale for measuring visual acuity.
- Extended treatment duration for aflibercept 8mg from 20 weeks to 24 weeks, in line with a recent licence change for the product.
- Off-label treatment duration of 3 weekly intervals for faricimab to enable flexibility in the dose scheduling to support the loading period.
- Locally agreed definition for capacity constraints included for SEL as a delay in scheduled injection date by more than 25%.

The presenter outlined the current local ophthalmology services and that the inclusion of aflibercept 8mg and faricimab within the pathway offers a solution to mitigate potential capacity constraints, as these treatment options have the potential to provide a longer treatment interval in comparison to biosimilar ranibizumab and aflibercept 2mg. The presenters informed the committee that Trusts will be expected to explore solutions to addressing capacity constraints before use of the longer acting agents is considered.

Committee members also noted a recommendation from the sub-group for the local commissioning of biosimilar ranibizumab and aflibercept 2mg outside of the NICE TA visual acuity criteria for the management of late wet active AMD (best-corrected visual acuity better than 6/12). NICE guideline (NG82) on the management of age related macular degeneration, recognises the use of anti-VEGFs

outside of the visual acuity criteria set in the associated NICE TAs and the national NHSE guidance supports use in line with NG82. The NHSE commissioning guidance delegated the decision on the use of anti-VEGFs in this setting to local commissioners. Eligible patients for biosimilar ranibizumab and biosimilar aflibercept 2mg in this setting is anticipated to be low and a negligible cost impact is anticipated as only biosimilar anti-VEGFs will be commissioned (ranibizumab or aflibercept 2mg when it is available).

From a cost perspective, implementation of the SEL medical retinal treatment pathway for wet AMD is within the financial threshold delegated to the committee. Implementation of the pathway is anticipated to be cost neutral or cost saving once biosimilar aflibercept 2mg implementation commences. Where clinically appropriate, there will be a preference for the use of aflibercept 8mg over faricimab, given its greater cost-effectiveness within the current treatment pathway. The use of anti-VEGFs in line with the pathway will be monitored using the wet AMD outcomes and monitoring framework.

Minor comments were raised in relation to clarifying the wording to describe the scenarios which do not count as a line of therapy and noting the use of biosimilar ranibizumab and aflibercept 2mg outside of the NICE TA visual acuity criteria for the management of wet AMD has been approved for local commissioning.

- **Aflibercept 2mg biosimilar formulary request**

This is a request for the formulary inclusion of aflibercept 2mg biosimilar intravitreal injection in adults with a “Red, Amber, Green” (RAG) category of Red (hospital only), once the preparation is available. The formulary inclusion request is in line with the existing indications on the SEL adult joint medicines formulary (JMF) approved for the originator product (Eylea®) as per the NICE TAs. This request has been discussed and approved via the ophthalmology medical retinal therapies sub-group.

Aflibercept 2mg biosimilar is expected to be available as a pre-filled syringe allocated to regions under a commercial in confidence national framework. It is also expected aflibercept 2mg biosimilar will be licensed for all aflibercept 2mg originator indications, except retinopathy of prematurity, as per information from the national Specialist Pharmacy Service (SPS). Aflibercept 2mg has been endorsed by the Royal College of Ophthalmologists and has a clear positioning as a first line option for the treatment of wet AMD in the NHSE commissioning guidance. Aflibercept 2mg biosimilar use for the indications retinal vein occlusion (RVO), diabetic macular oedema (DMO) and choroidal neovascularisation (CNV) is supported in line with the licensed indications, national pathways are under development for DMO and RVO.

From a cost perspective, the formulary inclusion of aflibercept 2mg biosimilar is within the financial threshold delegated to the committee and will result in cost savings to the local health economy. For wet AMD, Trusts aim to switch 90% of existing patients on aflibercept 2mg to the biosimilar preparation and aim to initiate 70% of new wet AMD patients on to a biosimilar preparation (aflibercept 2mg or ranibizumab).

- **Formulary request and cost modelling for aflibercept 8mg in wet AMD**

The request for the formulary inclusion of aflibercept 8mg biosimilar intravitreal injection in adults as Red (hospital only) for the management of wet AMD has been discussed and approved via the ophthalmology medical retinal therapies sub-group. Aflibercept 2mg is readily available and is approved by NICE and licensed for wet AMD and DMO. However, a national DMO guideline is under development and a separate request for the use of aflibercept 8mg in this setting will be presented at a future IMOC meeting. There is no planned NICE TA for aflibercept 8mg, however NICE acknowledges that aflibercept 8mg is as clinically equivalent and cost-effective in comparison to aflibercept 2mg and therefore should be considered for routine commissioning in this setting. Aflibercept 2mg will remain as a first line option for all new patients with wet AMD and aflibercept 8mg will be a preferred second choice option ahead of faricimab for the following patient cohorts:

- Existing patients not responding sufficiently to aflibercept 2 mg or faricimab intravitreal injections after initially receiving a loading course of 3 months
- Patients already established on aflibercept 2mg or faricimab that are currently on 4-7 weekly intravitreal injections
- Patients naïve to anti-VEGF treatments who may be better managed with the least number of injections which will outweigh the cost, as outlined in the national pathway.

From a cost perspective the formulary inclusion of aflibercept 8mg is within the financial threshold delegated to the committee and is anticipated to be cost neutral to cost saving when compared to the alternative option of faricimab, which aflibercept 8mg will substitute against.

Since the agenda paperwork was circulated, a national framework for the use of the anti-VEGFs has been shared with NHS Trusts. This sets out the commercial in confidence pricing for the anti-VEGFs.

In relation to cost modelling for various aspects of the pathway, committee members were asked to note that this was challenging for the sub-group to construct given the differing factors that will impact on the way the treatments are used. This includes factors such as differing intervals for treatment and some patients requiring bilateral treatment. In view of this, a number of assumptions have been applied to the cost modelling.

- **Outcomes and monitoring framework 2025/26**

The outcomes and monitoring framework developed and approved through the medical retinal therapies subgroup was presented. The framework aims to provide assurance on the use of anti-VEGFs in wet AMD in line with the pathway and was included in the IMOC pathway consultation. The framework focuses on four key performance indicators, including use of best value anti-VEGFs.

Committee members approved the following by consensus:
- SEL medical retinal treatment pathway for wet AMD pending updates to the pathway in line with the discussion.
- Formulary inclusion and commissioning of biosimilar ranibizumab and biosimilar aflibercept 2mg for the management of wet AMD where best-corrected visual acuity is better than 6/12 (outside of NICE TA criteria)
- Formulary inclusion of aflibercept 2mg biosimilar in line with the existing approved indications for the originator product (Eylea®) as per NICE TAs
- Formulary inclusion of aflibercept 8mg as a preferred second line treatment option for the management of wet AMD.
- Wet AMD outcomes and monitoring framework 2025/26

ACTION: Wet AMD pathway to be updated in line with discussions and progressed for ratification via IMOC Chair's approval
ACTION: Biosimilar ranibizumab and aflibercept 2mg for the management of wet AMD where best-corrected visual acuity is better than 6/12 to be added to the SEL adult JMF
ACTION: Aflibercept 2mg biosimilar to be added to the SEL adult JMF in line with the existing approved indications for the originator product (Eylea®)
ACTION: Aflibercept 8mg to be added to the SEL adult JMF as a preferred second line treatment option for the management of wet AMD

ii. Impact of faricimab for treating visual impairment caused by macular oedema after retinal vein occlusion

In line with NICE TA 1004 published in September 2024, faricimab provides another option alongside aflibercept 2mg intravitreal injections in this setting. Aflibercept 2mg has been used in this setting since late 2016 and faricimab has been in use locally under this NICE TA indication since December 2024. From a cost impact perspective, the local use of faricimab in this setting is within the financial threshold delegated to the committee. At the present time, faricimab is priced similarly

to aflibercept 2mg and this is a substitution cost or associated with a cost reduction when considering the whole pathway cost (not just the drug cost) due to the reduced frequency of injections with faricimab in comparison to aflibercept 2mg. However, in view of the upcoming biosimilar aflibercept 2mg launch, the use of faricimab is likely to be recommended as a second line treatment option nationally after biosimilar ranibizumab or biosimilar aflibercept 2mg.

Committee members noted the neutral cost impact of faricimab for treating visual impairment caused by macular oedema after retinal vein occlusion in line with NICE TA 1004, with the potential for savings in the future when biosimilar 2mg aflibercept is available. Members noted that once the national pathway for RVO is published it will be adapted for SEL by the medical retinal therapies group and presented at IMOC for approval in the future.

The presenters were thanked for their extensive work on the documents presented.

5. Updated co-morbid insomnia treatment pathway

The author was in attendance to present this pathway which has been updated following the formulary application approval at the April 2024 meeting for prazosin in nightmare disorder associated with post-traumatic stress disorder (PTSD). The formulary application requested an update to the co-morbid insomnia pathway to amend trazodone and agomelatine from second and third line to first- and second-line options, specifically in people with PTSD associated nightmare disorder. These two agents are used as insomnia treatments, not treatments for PTSD associated nightmares for this patient cohort as melatonin is not a suitable 1st line option in these patients.

The co-morbid pathway has also undergone the following main updates:

- Clarification regarding the place in therapy for Cognitive Behavioural Therapy (CBT-I)
- Inclusion of daridorexant for the management of chronic insomnia in line with NICE TA922
- Daridorexant and melatonin for its licensed indication noted as first line treatment for the management of chronic insomnia and off-label melatonin (2mg at night up to 6mg if required) moved to second line treatment
- Inclusion of a supportive information key, which includes the use of trazodone and agomelatine as first and second line options for the management of chronic insomnia in people with PTSD associated nightmare disorder

A query was raised about whether the pathway applies to both primary care and the tertiary sleep centre, and whether the sleep centre manages acute insomnia. The presenter clarified that the pathway is primarily for the sleep centre, which handles complex, co-morbid cases. GPs typically follow NICE Clinical Knowledge Summaries (CKS) guidance on insomnia for primary care management. The sleep centre does treat acute insomnia when it co-occurs with other sleep disorders. A follow-up question was raised noting that the pathway includes treatments for acute and chronic insomnia commonly initiated in primary care. GP members recommended that the pathway be applicable to both primary care and the sleep centre. The presenter agreed and confirmed the pathway will be updated to reflect that primary care can manage acute and early-stage chronic co-morbid insomnia.

In line with the request to reflect co-morbid insomnia management across care settings. An amendment was requested to reposition melatonin (off label) - Amber 2 to reflect all sleep centre-initiated treatments at the same position within the pathway. The presenter agreed the pathway will be updated to reflect this amendment.

An update was also requested to position daridorexant and melatonin modified release (M/R) equally as first-line options for chronic insomnia, with a recommendation to trial the alternative first line treatment if the initial treatment is ineffective. This is in acknowledgement that melatonin M/R is already in use as a first line option (off label).

Committee members noted formulary recommendation 142 and 143 associated with the co-morbid pathway require minor updates following updates to the pathway. Committee members agreed the

formulary recommendations updated post meeting can be ratified via IMOC Chair's action without presentation back to the committee.

Committee members approved the updated co-morbid pathway by consensus pending updates to the pathway in line with the discussion.

ACTION: Co-morbid pathway to be updated in line with discussions and progressed for ratification via IMOC Chair's approval
ACTION: Formulary recommendation 142 and 143 to be updated and progressed for ratification via IMOC Chair's approval

6. Updated stimulant therapy and anti-cataplectic agents in the management of narcolepsy (+/- cataplexy) and idiopathic hypersomnia in adults share care guideline

The author was in attendance to present this item to request alignment of the shared care guideline (SCG) with the formulary recommendations and SEL adult JMF entries for methylphenidate and dexamphetamine in this setting. The formulary recommendations and SEL adult JMF entries for methylphenidate and dexamphetamine in this setting state the initiation and minimum supply of methylphenidate and dexamphetamine should be 6 months under the shared care arrangements. However, this should be 3 months in line with the updated SCG approved by the committee in March 2023 and current practice within the sleep centre. The presenter clarified that whilst most patients will be initiated and stabilised on treatment and transferred to primary care at 3 months, some patients may take longer to stabilise on treatment and will remain under specialist until their treatment is stabilised. A note to this effect has been included in the updated SCG.

As the SCG also required a general review and update, committee members noted minor updates to the SCG were also undertaken including aligning to the most up to date IMOC SCG template.

A question was raised regarding whether reference to a specific methylphenidate M/R preparation is necessary within the SCG now that branded generic formulations are available. The presenter clarified it is best practice to prescribe methylphenidate M/R by brand, however there are instances where an alternative brand is required due to reasons such as supply disruption. A suggestion was made to provide a link to the national SPS shortages resource "Prescribing and switching between modified-release methylphenidate." The presenter agreed to include a hyperlink to the SPS resource within the SCG. Committee members noted formulary recommendation 046 and 047 for methylphenidate and dexamphetamine in this setting require minor updates to align with the agreed transfer of prescribing arrangements within the SCG. Committee members agreed the formulary recommendations updated post meeting can be ratified via IMOC Chair's action without presentation back to the committee.

Committee members approved the updated stimulant therapy and anti-cataplectic agents in the management of narcolepsy (+/- cataplexy) and idiopathic hypersomnia in adults SCG by consensus pending updates to the SCG in line with discussions.

ACTION: Shared care guideline to be updated in line with discussions and progressed for ratification via IMOC Chair's approval
ACTION: Formulary recommendation 046 and 047 to be updated and progressed for ratification via IMOC Chair's approval

7. SEL Acute Provider Collaborative (APC) primary and secondary care orthopaedic guidelines: suspected acute knee injury (IMOC is approving the medicines content only)

The lead authors from the APC were in attendance to present the item. The presenters outlined the work to develop the guideline which supports the diagnosis and management of suspected acute knee injury. The guidelines were circulated for consultation with the IMOC as well as a broader consultation including the Local Medical Committee (LMC). The medicines content of the guideline is limited with only one reference to the CKS topic on analgesia. Once approved, there are plans to

launch and promote the guideline alongside a new acute injury referral form to support the use of the guideline within primary care.

Feedback was provided in relation to better signposting within the guideline recommending over the counter analgesia for patients in this setting. The presenters agreed to update the guideline. A comment was raised about the implementation plan for the guideline. Presenters explained that a new acute injury referral form has been developed to standardise access to secondary care fracture and acute knee clinics. These clinics are currently underused due to limited GP awareness, leading to unnecessary accident and emergency (A&E). referrals. The new guideline and acute injury referral form will help to improve access to specialist care and support GPs in managing acute knee injuries.

A question was raised about assessing acute knee injuries in primary care, as these patients are often referred to A&E. The presenter explained that some patients can be managed in GP settings and referred to the acute knee clinic, while others may still require A&E. The guideline supports GPs in identifying the most appropriate referral pathway.

Committee members approved the SEL APC primary and secondary care orthopaedic guidelines: suspected acute knee injury (medicines content only) by consensus pending updates to the guideline in line with discussions

ACTION: Updated SEL APC suspected acute knee injury guideline to be updated in line with discussions and progressed for ratification via IMOC Chair's approval

8. Formulary recommendations:

- **New - drospirenone (Slynd®) as a second-line progestogen only contraceptive pill**

This formulary recommendation has been drafted following the approval of drospirenone (Slynd®) at the August IMOC meeting. The formulary recommendation was shared with the triage panel for comments, no comments were received. Committee members approved the formulary recommendation for drospirenone (Slynd®) as a second-line progestogen only contraceptive pill by consensus.

- **Updated - 131 doxylamine succinate 10mg/pyridoxine hydrochloride 10mg (Xonvea®) for the treatment of nausea and vomiting in pregnancy**

This formulary recommendation has been updated following the approval to recategorise Xonvea® as Green in this setting and removal of the time limit associated with the recommendation. The formulary recommendation was shared with the triage panel for comments, the following comments were received:

- Inclusion of a note that the amber 1 recommendation for the use of Xonvea® for the pre-emptive management of hyperemesis gravidarum may be from a previous pregnancy i.e. within a discharge letter and does not require a new recommendation from a specialist to enable initiation in primary care
- Clarify that the additional treatments noted for the pre-emptive management of hyperemesis gravidarum are also categorised as Amber 1

A comment was raised that it would be useful to note that the formulary recommendation is not for pre-emptive use and include the information on the pre-emptive management of hyperemesis gravidarum earlier in the recommendation.

Committee members approved the updated formulary recommendation for Xonvea® for the treatment of nausea and vomiting in pregnancy by consensus, pending updates to the recommendation in line with the discussion.

ACTION: Updated 131 formulary recommendation to be amended in line with discussions and progressed for ratification via IMOC Chair's approval

9. Primary care guidance for managing medicines with teratogenic potential that require pregnancy prevention programme (PPP)

The author was in attendance to present this item which has been developed in response to the national MHRA patient safety alerts regarding sodium valproate, valproic acid, and valproate semisodium (collectively referred to as valproate) in November 2023 and topiramate in June 2024. The national patient safety alerts requested ICBs to coordinate a system-wide response to the new regulatory measures. The guidance underwent IMOC consultation and earlier iterations of the guidance has been reviewed by the ICB Primary Care Medicines Safety group.

A comment was raised regarding a review of the statement which notes that the risk of pregnancy once a woman reaches the age of 55 is rare and contraception can be stopped. The Faculty of Sexual and Reproductive Healthcare (FSRH) guidance suggests that although a natural decline in fertility occurs with age and spontaneous pregnancy is rare after age 50, effective contraception should be maintained until menopause to avoid unintended pregnancies. The presenter agreed to review and update the statement within the guideline accordingly. A query was raised by the presenter in relation to defining an individual of childbearing potential as a person who has a uterus and ovaries and is pre-menopausal. Committee members agreed with this definition and the presenter agreed to update the guideline accordingly.

Committee members approved the primary care guidance for managing medicines with teratogenic potential that require PPP by consensus pending updates to the guidance in line with the discussion.

ACTION: Primary care guidance for managing medicines with teratogenic potential that require PPP to be amended in line with discussions and progressed for ratification via IMOC Chair's approval

10. Formulary submission: Metformin as prevention and reversal of weight gain in adults prescribed antipsychotics

This formulary submission originates from an Honorary Consultant Psychiatrist and Consultant Pharmacist and requests the off-label use of metformin for the prevention of weight gain in adults prescribed clozapine and olanzapine and the reversal of weight gain in adults prescribed any antipsychotic. The application requests an Amber 2 RAG category for the use of metformin in this setting after 6 months prescribing by the mental health team.

- **Evidence review**

The Formulary Pharmacist provided an overview of the evidence base - 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 metformin in this setting. The information presented also included the estimated resource impact for use of metformin. The resource impact of the submission is within the financial threshold delegated to the committee.

Current guidelines, including the NICE clinical guideline 178 (CG178) on the management of psychosis and schizophrenia in adults (2014), suggest that individuals taking antipsychotics should be provided with lifestyle interventions including health eating and physical activity programme. The 2016 British Association for Psychopharmacology (BAP) guidelines on the management of weight gain, metabolic disturbances and cardiovascular risk associated with psychosis and antipsychotic drug treatment also recommend lifestyle interventions for the management of weight gain in this setting, alongside interventions such as switching antipsychotic treatment. The 2016 BAP guidelines also recommend metformin as an adjunct treatment to attenuate or reduce weight gain following antipsychotic medication. However, both NICE and BAP guidelines do not directly address the prevention of antipsychotic-induced weight gain.

The Maudsley Prescribing Guidelines in Psychiatry recommend considering pharmacological intervention only after behavioural strategies and switching to alternative treatments with lower propensity for weight gain have failed or where obesity presents a clear, immediate physical risk to

the patient. The Maudsley guidelines also state that metformin is now considered to be the drug of choice for prevention and treatment of antipsychotic-induced weight gain.

Metformin in this setting is recommended when weight gain has reached either ≥2 kilograms (kg) or ≥3% of baseline weight, whichever is smaller. Alongside metformin, advice on behavioural interventions, such as diet and physical activity, will also be offered to patients.

The evidence supporting metformin in this setting primarily comes from a Cochrane systematic review of 17 randomised controlled trials (RCTs) involving 1,388 participants with schizophrenia. Five studies (232 patients) specifically evaluated metformin versus standard care, with three using olanzapine (none used clozapine). The average study duration was approximately 12 weeks (range 6 – 24 weeks), therefore no outcomes measuring long term use were reported. Results showed a statistically significant average weight reduction of 4 kg (mean difference -4.03 kg; 95% confidence interval [CI] -5.78 to -2.28; I2 = 0%).

A systematic review with a meta-analysis of 14 RCTs (1,126 patients) evaluated the impact of initiating metformin versus placebo in individuals with schizophrenia starting antipsychotic treatment. The atypical antipsychotics used included risperidone, olanzapine, and clozapine. Over an average of 15 weeks, metformin significantly reduced body weight by 3.12 kg (95% CI −4.22 to −2.01kg; I2=58%), particularly in antipsychotic-naïve patients (−3.28 kg - 95% CI −4.76 to −1.81kg; I2=74%). Improvements were also seen in blood glucose, total cholesterol, and triglycerides, though no significant changes were observed in high density lipoprotein (HDL), low density lipoprotein (LDL), or waist circumference. Despite the evidence suggesting that metformin effectively mitigates antipsychotic-induced weight gain, its impact on long-term cardiovascular outcomes remains unclear.

From a safety perspective, metformin can decrease vitamin B_{12} absorption, prompting a safety alert regarding monitoring B_{12} levels. In June 2022, the MHRA produced a Drug Safety Update highlighting the common occurrence of decreased vitamin B_{12} levels, or vitamin B_{12} deficiency in patients on metformin treatment, especially in those receiving a higher dose or longer treatment duration, and in those with existing risk factors.

- **Applicant's presentation**

The applicant was in attendance to present the submission and field any questions. The applicant's declaration of interest was noted. The applicant summarised the application noting that individuals with severe mental illnesses, such as schizophrenia, often experience an increased mortality of approximately 20 years earlier in comparison to the general population, primarily due to obesity-related conditions including cardiovascular disease. Antipsychotic medications are significant contributors to weight gain in this patient cohort, with ~85% of patients gaining at least 7% in weight within a year of starting treatment. An average weight increase of 12kg annually is also observed with certain antipsychotics such as clozapine and olanzapine. It is anticipated that including metformin in the formulary in this setting will support greater collaboration and consistency in patient care.

A comment was raised regarding the monitoring of weight loss for this patient cohort in primary care. The application recommends measuring weight loss in kg; however, weight loss is commonly measured as a percentage reduction in primary care. The presenter confirmed that measuring weight loss as a percentage reduction can be applied to patients prescribed metformin in this setting, with treatment discontinuation advised if weight loss is less than 5% in a 3-month period.

A query was raised regarding the recommended daily dose of 1 gram (g) for metformin and whether this dose should be adjusted when a patient's antipsychotic dose is changed. The presenter clarified that the recommended 1g daily dose of metformin is based on RCT data. While higher doses may be effective if tolerated, current evidence indicates there is no need to adjust the dose when a patient's antipsychotic dose is modified.

A request was made to clarify the estimated number of patients eligible for metformin in this setting across SEL, including the data source and whether this reflects all SEL patients within the local mental health Trusts. The presenter confirmed the data is from local Trust databases and also advised they require updating following a recent audit of electronic patient records. However, this figure may also include patients outside of SEL and does not include patient numbers from all local mental health Trusts. The presenter agreed to confirm the eligible SEL patient numbers outside of the meeting and the cost impact will be updated accordingly. It was noted that patient numbers are expected to remain stable or decline as prescribing of metabolically active antipsychotics is expected to reduce over time.

A comment was raised whether any patient outcomes such as improved metabolic control and the prevention of type 2 diabetes has been observed in the patient cohort who have been treated thus far with metformin in this setting. The presenter reported that metformin has been initiated in 40 patients over the last few months, with weight remaining stable. While long-term outcomes are yet to be observed, only one patient discontinued due to intolerance, and most patients expressed appreciation for the attention to their physical health alongside their mental health care.

Clarification was requested on the criteria for initiating metformin, including the role of antipsychotic choice and whether the patient's body mass index at the start of antipsychotic therapy would determine if metformin should be initiated. The presenter explained that clozapine, used for treatment-resistant schizophrenia and the only licensed option in this setting, is associated with significant weight gain and metformin will likely be offered to all clozapine patients. While olanzapine is being used less frequently as a first-line option, it remains commonly used due to its efficacy. Locally, lower cardiometabolic risk antipsychotics such as aripiprazole and cariprazine are preferred where appropriate. In line with Maudsley guidance, switching to a lower cardiometabolic risk antipsychotic should be considered before initiating metformin.

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

Committee members discussed the application and members confirmed support of the application and acknowledged there is a patient cohort who could benefit from metformin as prevention and reversal of weight gain in adults prescribed antipsychotics. The longer-term outcomes from reducing the impact of weight gain from antipsychotics would lead to broader benefits in the future.

Committee members approved the following by consensus as Amber 2 (specialist initiation) for formulary inclusion of metformin (off label use):

- prevention of weight gain in adults prescribed clozapine and olanzapine
- reversal of weight gain in adults prescribed any antipsychotic

ACTION: Formulary recommendation to be drafted and presented at a future meeting
ACTION: Metformin for the prevention of weight gain in adults prescribed clozapine and olanzapine and reversal of weight gain in adults prescribed any antipsychotic to be added to the SEL adult JMF (off label use)

11. Opportunities from generic dapagliflozin:

- **Proposal for preferred choice of sodium glucose co- transporter 2 inhibitor (SGLT2i)**
- **Draft position statement**

The author presented this item outlining the request to use generic dapagliflozin as the locally preferred SGLT2i in new patients for the treatment of type 2 diabetes (T2DM), symptomatic chronic heart failure (CHF), and chronic kidney disease (CKD) in line with the indications listed in the SEL adult JMF, SEL IMOC and CESEL guidance. This request has been endorsed by the SEL Medicines Value Group and the diabetes and cardiovascular sub-groups of the IMOC.

Dapagliflozin is now available as a generic medication and at much lower acquisition cost than other SGLT2i. There are currently four SGLT2i's on the UK market – canagliflozin, dapagliflozin,

empagliflozin and ertugliflozin, all with varying licensing approvals. Dapagliflozin and empagliflozin are the only SGLT2i's licensed for T2DM, CKD and symptomatic CHF.
The September 2025 Drug Tariff highlights that the price of dapagliflozin has reduced and further reductions in cost are expected over the next few months. Based on previous patent expiries, the reduction in price can be anywhere between 30-80% from the baseline originator branded product cost. The potential cost saving from generic dapagliflozin excludes combination products but includes savings from switching locally prescribed branded dapagliflozin items to generic.

A position statement has been developed to support adoption of generic dapagliflozin as the locally preferred SGLT2i as well as outline considerations for prescribers when considering prescribing generic dapagliflozin.

A query was raised regarding clinically justified exceptions to prescribing dapagliflozin in complex heart failure, which may warrant the use of empagliflozin as the preferred SGLT2i. The author confirmed this will be clarified with the specialist heart failure team whilst noting that all SGLT2i's approved by NICE remain on the local formulary. There is always scope to use an alternative SGLT2i in patients where dapagliflozin is not clinically appropriate.

Committee members approved the position statement and the use of generic dapagliflozin as the locally preferred SGLT2i in new patients for T2DM, symptomatic CHF and CKD by consensus.

12. Standing items

- Formulary submissions tracker

Noted.

- NICE Technology Appraisal (TA) Guidance Summary – *ICS and NHSE attributed medicines*:

The summary was noted, and RAG categories were agreed by consensus, where it was possible to confirm the RAG status.

- For NICE TA 1004 - faricimab for treating visual impairment caused by macular oedema after retinal vein occlusion, in line with discussions earlier in the meeting, the costs associated with implementing this NICE TA is noted as cost neutral to cost saving.
- For NICE TA 1087 - betula verrucosa for treating allergic rhinitis or conjunctivitis caused by tree pollen, Trust teams to assess cost impact, and report estimate costings at the next meeting and propose desired categorisation

ACTION: Trust teams to provide cost impact modelling and proposed RAG category for the use of betula verrucosa under NICE TA1087

- For information and noting:
- Adult and paediatric formulary updates - noted by committee members.

13. Any other business

IMOC dates for the next 3 months

Date	Time	Venue
Thursday 16th October 2025	2pm – 4:30pm	MS Teams
Thursday 20th November 2025	2pm - 4.30pm	MS Teams
Thursday 18th December 2025	2pm - 4.30pm	Hybrid (MS Teams/in person)