South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
16th October 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.

The committee reviewed an update on an action for the use of alimemazine in paediatric dystonia with poor sleep and/or vomiting. As only a small number of children have been treated since approval in September 2023, outcome data remain limited. The applicant requested that alimemazine remain classified as Red. The committee agreed by consensus to remove the time limit on approval and the requirement for further outcome data.
ACTION: Updated formulary recommendation to be presented at IMOC

4. Self-care and Low Priority Prescribing (LPP) sub-group update including the self-care week communication plan:

A member of the self-care and low priority prescribing (LPP) subgroup was in attendance to present an update, including prescribing data, communication plans for Self-care Week, and a proposal to clarify formulary guidance on non-NHS travel vaccines. The presenter explained that the subgroup aims to reduce primary care prescribing of self-care and LPPs, support NHS Pharmacy First, and encourage public behavioural change. Data showed over £13.6 million spent on self-care products and £1.5 million on LPPs in 2024/25, with a downward trend but ongoing need for monitoring.

The subgroup's work plan focuses on reducing spend on over the counter (OTC) medicines and LPPs through monthly bulletins, targeted local messages, and alignment with national campaigns. Topics are timed seasonally, and recent efforts included bulletins on bath/shower preparations and omega-3 fatty acids. In relation to travel vaccines, the presenter proposed adding a statement to the SEL adult Joint Medicines Formulary (JMF) to clarify that non-NHS travel vaccines are not prescribable on the NHS.

The communication plan for Self-care Week (17–23 November) was shared with the committee for information and will include articles, posters, and banners. The campaign will be promoted across boroughs and social media, with collaborative efforts linking to other health campaigns such as Pharmacy First, Stay Well This Winter, and World Antibiotic Awareness Week. A key focus will be on promoting NHS Pharmacy First and local community pharmacy services.

The committee discussions included:

- Agreement that the travel vaccine statement should be placed in the vaccine monograph's notes, not under individual listings.
- Confirmation that, from the NHS perspective, both leisure related travel and work related travel are considered as travel and prescribing non-NHS vaccines is not recommended in both scenarios.
- Acknowledgement that consistent messaging is needed across community pharmacies to encourage OTC purchasing where clinically appropriate.

- Reassurance to members that the OTC purchase recommendation does not override GP discretion in prescribing for long-term conditions (for example, paracetamol in chronic rheumatological conditions).

Committee members approved by consensus the inclusion of a statement within the SEL adult JMF noting that certain vaccines are not prescribable on the NHS for the purpose of travel pending an update to the proposed statement. Committee members agreed the updated statement should be included within the notes section of the vaccines monograph in the SEL adult JMF.

ACTION: SEL adult JMF statement for non-NHS vaccines to be updated in line with discussions and progressed for ratification via IMOC Chair's approval
ACTION: Statement for non-NHS vaccines to be added to the SEL adult JMF within the notes section of the vaccines monograph

5. Intravenous zoledronic acid 4mg for osteoporosis in men and postmenopausal women with impaired renal function – off label (creatinine clearance between 30-35 ml/min, or estimated glomerular filtration rate >30ml/min)

This formulary submission (from Ortho-Geriatricians)requests the off-label use of intravenous (IV) zoledronic acid 4mg for osteoporosis (including corticosteroid induced osteoporosis) in men and postmenopausal women with impaired renal function. The application requests a Red (hospital only) 'Red Amber Green' (RAG) category for the use of IV zoledronic acid 4mgn (off-label) as a single dose or yearly infusion for 3 years or longer in certain patients or 18 monthly infusions based on individual cases for patients with a creatinine clearance (CrCl) between 30-35 ml/min, or in some cases estimated glomerular filtration rate (eGFR) >30ml/min/1.73 m^2; in the following patient cohorts:

- First line treatment for secondary prevention of a fragility fracture or
- Primary and secondary prevention as per SEL osteoporosis treatment pathway or
- In patients with limited life expectancy of less than 12 months

➢ **Evidence review**

The Formulary Rotational 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 IV zoledronic acid 4mg in this setting. The information presented also included the estimated resource impact for use of IV zoledronic acid 4mg. The resource impact of the submission is within the financial threshold delegated to the committee.

The National Osteoporosis Guidelines Group UK (NOGG) and National Institute for Health and Care Excellence (NICE) recommend antiresorptive therapies such as IV zoledronic acid for men age ≥ 50 and postmenopausal women with high to very high risk of fracture with/without glucocorticoid-induced osteoporosis. In line with NOGG, oral bisphosphonates and IV zoledronic acid are considered the most cost-effective interventions, with IV zoledronic acid recommended as a first-line treatment following hip fracture.

In line with the local osteoporosis treatment pathway IV zoledronic acid is considered in patients with a CrCl above 35ml/min and if oral alendronic acid/risedronate is contraindicated. IV zoledronic acid is generally recommended for 3 years (or 3 doses for patients on extended 18 monthly dosing intervals). Annual dosing schedules, longer durations of treatment, for at least 6 years, are recommended in a defined patient cohort. The local pathway also recommends lower dose and longer spacing between IV zoledronic acid, for example, a single dose may be appropriate to provide appropriate fracture protection for a frail elderly individual with life expectancy less than 3 years. At present, denosumab is the anti-resorptive treatment of choice in patients with osteoporosis with a CrCl below 35 mL/min.

In 2010, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a patient safety alert regarding the renal adverse effects of IV zoledronic acid 5mg, including fatal cases of adverse

effects. Most cases occurred after the first dose and were predominantly in patients with pre-existing renal dysfunction or risk factors such as advanced age, use of nephrotoxic drugs or diuretics, or dehydration. A UK consensus statement published in Age and Ageing (2023) highlighted the underuse of IV zoledronic acid for secondary fracture prevention following hip fracture in older adults. The statement acknowledged the lack of randomised controlled trial (RCT)-level evidence for patients with CrCl 30–35 ml/min but advised that potential renal risks should be balanced against fracture prevention benefits. It concluded that IV zoledronic acid, may be considered on a case-by-case basis in this group, with appropriate precautions.

The evidence base for the use of IV zoledronic acid 4mg in this setting is primarily based on two HORIZON (Health Outcomes and Reduced Incidence with IV zoledronic acid Once Yearly) RCTs. The HORIZON pivotal fracture trial (over 7,500+ patients, 3 years) showed annual 5 mg IV zoledronic acid significantly reduced vertebral fractures by 70% and hip fractures by 41% (95% CI 0.42–0.83) with only transient renal changes in patients with CrCl >30 ml/min. The HORIZON recurrent fracture trial (over 2,000 post-hip fracture patients) confirmed fracture reduction and found renal and cardiovascular safety comparable to placebo.

Advice from the MHRA and in the British National Formulary (BNF) state that eGFR is generally an acceptable measure of renal function, but may overestimate compared to CrCl, especially in patients over the age of 75 or with extreme body weight and CrCl is preferred in these cases. A large retrospective study found eGFR and CrCl equally predictive of acute kidney injury, suggesting the CrCl 35 ml/min cut-off may be overly restrictive. Treatment decisions should be based on individual risk–benefit assessments rather than strict CrCl thresholds.

From a safety perspective regarding non-renal adverse effects, the MHRA has issued several warnings about rare adverse effects of IV zoledronic acid (atypical femoral fractures, osteonecrosis of the jaw, and osteonecrosis of the external auditory canal). These side effects were not consistently monitored across studies identified. The HORIZON studies did not report any instances of osteonecrosis of the jaw.

- **Applicant's presentation**

The co-applicant was in attendance to present the submission and field any questions. The second co-applicant was unable to attend the meeting. The applicant's declaration of interest was noted. The Formulary Pharmacist clarified that the MHRA drug safety alert regarding the renal adverse effects of IV zoledronic acid 5mg does not prohibit its use in patients with a CrCl below 35 ml/min. Rather, it advises caution in patients with poor renal function, those who are dehydrated, or those on nephrotoxic medications. The off-label use of IV zoledronic acid 4mg in this setting has been discussed with medicines safety and governance colleagues, there were no concerns raised regarding compliance with the MHRA drug safety alert. However, it is recommended appropriate safeguards are in place such as ensuring patients are well hydrated and excluding patients on nephrotoxic drugs.

A query was raised regarding how the appropriate safeguards pre-infusion for IV zoledronic acid would be carried out in practice. The applicant explained that the majority of hip fracture patients usually stop antihypertensive medication and diuretics during their admission until they are discharged. Additionally, the majority of this patient cohort are not commonly prescribed nephrotoxic medications. Hydrating patients' pre-infusion will also be carried out in all patients.

A question was raised in relation to the minimum life expectancy required for patients to be considered eligible for treatment with IV zoledronic acid in this setting. The presenter confirmed treatment with IV zoledronic acid would be considered only for those with an estimated life expectancy of at least 6 -12 months, and this assessment would be made during clinic review or as in-patient.

A comment was raised around the impact of using IV zoledronic acid in this setting on infusion suites which are often associated with capacity issues. The applicant confirmed as they are only requesting the use of IV zoledronic acid as a one-off dose in patients with a limited life expectancy

already admitted as an inpatient, there should be no impact on infusion suite capacity. For patients with reduced renal function who require long-term treatment, denosumab may be more appropriate. It was noted that denosumab biosimilars are expected early next year, which may change the cost impact estimates, which compared IV zoledronic acid against denosumab. The Formulary Pharmacist clarified that the attending applicant specifically led on the proposal to use IV zoledronic acid as a single dose in patients with limited life expectancy. Other local Trusts expressed interest in using the IV zoledronic acid 4 mg for longer-term osteoporosis treatment.

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

Committee members discussed the application and members confirmed the application for the use of IV zoledronic acid as a single dose in patients' post-fracture with limited life expectancy (6 – 12 months) could be the only aspect of the application considered for approval. Committee members agreed the application for the use of IV zoledronic acid 4mg as yearly infusions for 3 years or longer or 18 monthly infusions for the primary and secondary prevention of osteoporosis will need to be re-presented at a future IMOC meeting with an applicant able to field the Committee's questions and queries. The Formulary Pharmacist confirmed members of the osteoporosis treatment pathway task and finish group* were supportive of the application and that some clinicians across other SEL Trusts may already be using IV zoledronic acid 4mg treatment in broader contexts, and it would be helpful to include views from these clinicians on their experience when the application is re-presented.
**Post meeting note: Although the application had not been shared with the osteoporosis task and finish group, individual clinicians on the group were supportive of the application.*

Committee members approved by consensus the use of IV zoledronic acid 4mg (off-label) as Red (hospital only) when used as a single dose post-fracture in patients with a life expectancy of approximately 6 to 12 months and a CrCl between 30-35 ml/min, or in some cases eGFR >30ml/min/1.73 m². The Trust will need to ensure appropriate governance and infrastructure is in place to deliver IV zoledronic acid safely in this patient cohort.

ACTION: Formulary recommendation to be drafted and presented at a future meeting
ACTION: SEL osteoporosis treatment pathway to be updated to include the use of IV zoledronic acid 4mg (off-label) as a single dose post-fracture in patients with a reduced life expectancy and impaired renal function
ACTION: IV zoledronic acid 4mg (off-label) as a single dose post-fracture in patients with a reduced life expectancy and impaired renal function to be added to the SEL adult JMF once the local pathway has been updated

6. Formulary request to include modafinil for the management of fatigue associated with multiple sclerosis (MS) off-label as Amber 2 (historical use request)

The applicant was in attendance to present this item which is a historical use request. In line with NICE guideline (NG220), modafinil is recommended for the pharmacological management of fatigue associated with MS (off-label), in cases where first-line, non-pharmacological interventions have been insufficient, with the request for an Amber 2 RAG category.

Fatigue in MS is typically managed through non-pharmacological measures, with other pharmacological options including selective serotonin reuptake inhibitors (SSRIs) such as sertraline as well as amantadine. The choice of treatment depends on a number of patient factors, SSRIs may be considered as the initial option if fatigue and depression are linked, which is common for majority of cases.

As per the MHRA drug safety alert for modafinil, it should not be used during pregnancy and women of childbearing potential must use effective contraception during treatment and for 2 months after stopping modafinil. The MHRA drug safety alert also recommends specific cardiovascular disease (CVD) related monitoring, in line with this, modafinil should be discontinued in patients who develop arrhythmia or moderate to severe hypertension. Modafinil is also cautioned in patients with a history of psychosis, depression or mania, abuse of alcohol, drugs, or illicit substances. The specialist team

will ensure patients will be monitored closely and advised to report any suspected adverse behaviours or thoughts.

In line with the Amber 2 categorisation request, patients will be seen by the specialist team to complete baseline investigations, discuss pregnancy and contraception, issue the first 3 month's supply and assess efficacy or tolerability and make any dose adjustments as necessary in this time frame. The specialist team will request a transfer of prescribing responsibility to the GP after 3 months when appropriate to do so. The specialist team will review MS patients every 6 months and will assess contraception status. However, it is important primary care clinicians also assess contraception status when prescribing is transferred to primary care.

From a cost perspective this formulary request is within the financial threshold delegated to the committee.

An extensive committee discussion followed, debating monitoring, shared care, and the proposed formulary RAG status. Concerns were raised about the complexity of monitoring for CVD and psychiatric side effects, the off-label nature of use, and the expectation for primary care to manage high-risk patients with limited experience. There was significant debate on whether to approve as Amber 2, Amber 3 (shared care), or Red. The presenter explained that the Amber 2 category is being proposed to align with the existing Amber 2 categorisation for amantadine in MS in this setting. Committee members shared opinions about the advice in the NICE guidance and the need for explicit monitoring protocols under shared care.

The presenter confirmed that in relation to the monitoring of high-risk patients, specifically those with a history of suicidal depression or illicit drug use, it is recommended GPs conduct welfare checks at the point of prescribing. Ideally these patients will have clinical contact at least every three months, alternating between primary and specialist care. The presenter also explained baseline CVD monitoring is carried out by the specialist team. On-going monitoring is not specified in the NICE guidance; however, reference was made to practice in areas, where CVD monitoring is done every 6 to 12 months. The presenter agreed to follow this up with the clinicians to confirm the need for regular CVD monitoring. A comment was raised that if CVD checks are required every six months or more frequently, it needs to be made clear how GPs are expected to carry this out, what actions to take if results are abnormal and who to contact for support.

A query was raised regarding the use of SSRIs such as sertraline in this setting and whether this request should also include the formulary inclusion of sertraline for fatigue associated with MS as this is not included within the SEL adult JMF. The presenter clarified that sertraline used in this setting is for fatigue associated with MS caused by depression. In line with this sertraline is being used for its licensed indication of depression and is included within the SEL adult JMF.

Committee members agreed that the desired Amber 2 category would not be appropriate for the reasons discussed and did not approve the Amber 2 request. The committee approved by consensus the formulary inclusion of modafinil for the management of fatigue associated with MS as Amber 3 (shared care).

ACTION: Shared care guideline to be developed and presented at a future IMOC meeting for discussion and approval
ACTION: Modafinil for the management of fatigue associated with MS to be added to the SEL adult JMF following approval of the shared care guideline

7. Lidocaine 5% plasters for post-operative pain control in a selected cohort of patients following surgery for neck of femur fractures (off-label)

This formulary submission originates from an Ortho-Geriatrician and requests the off-label use of lidocaine 5% plasters for post-operative pain control in a select cohort of patients following surgery for neck of femur (NOF) fractures. The application requests a Red (hospital only) RAG category for the use of lidocaine 5% plasters with up to 5 days maximum use in this setting as follows:

- Operative management with intramedullary (IM) nail *and*

- Significant uncontrolled post-operative pain not controlled with regular paracetamol and
- opiates as per Trust NOF pain pathway protocol *and*
- Unmanageable opioid-related side effects including oversedation and difficult to manage delirium

➢ **Evidence review**

The Formulary Pharmacist presented 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 lidocaine 5% plaster in this setting. The information presented also included the estimated resource impact for use lidocaine 5% plaster. The resource impact of the submission is within the financial threshold delegated to the committee.

Lidocaine 5% plasters are licensed for the treatment of neuropathic pain in post-herpetic neuralgia, but are used outside of this specific indication, though the evidence for benefit in off-label use is less clear. NHS England have recommended lidocaine 5% plasters should not be commonly prescribed in primary care outside of the licensed indication due to the limited evidence of benefit. Locally, lidocaine 5% plasters are currently approved off-label for the management of focal neuropathic pain with allodynia, restricted to initiation by a pain specialist and as a 5-day course of analgesia following thoracotomy surgery.

In line with the application, the standard pain management pathway for this patient cohort following hip fracture surgery includes a fascia iliac block, regular paracetamol, and opioid analgesics, with daily review of pain and liaison with the pain team, as necessary. Opioids are typically tapered from day three post-operation with the aim of discontinuation by days five to seven.

No studies specifically evaluated lidocaine 5% plasters after hip fracture surgery. Evidence from broader post-operative settings suggests modest analgesic benefits and high heterogeneity. Two systematic reviews of 27 RCTs (total 1,457 patients) found lidocaine plasters reduced pain scores at 6 - 48 hours post-surgery, though opioid-sparing effects were inconsistent and often not clinically meaningful. Despite some evidence, that lidocaine plasters provide modest analgesic effects after surgery the overall evidence base is limited by the lack of trials in the specific context of hip fracture surgery. The heterogeneity across studies, including variation in types of surgery, patch use, and small sample sizes, limits the applicability of the findings in this setting. Additionally, no cost-effectiveness analyses were identified, and there is no published guidance on managing ongoing pain should the pain persist beyond the initial five-day lidocaine 5% plaster course.

➢ **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 shared the application for the use of lidocaine in this setting stems from 18 months of quality improvement work at the Trust to improve the care standards for NOF fracture patients. While this cohort is underrepresented in clinical research, data from the National Hip Fracture Database supports the benefit of lidocaine 5% plasters. The applicant explained that lidocaine plasters have been used in a small, defined cohort locally to reduce opioid use in older complex frail patients with IM nails but acknowledged the absence of published evidence. It may also be reasonable to extrapolate the use of lidocaine 5% plaster in this setting from data in other surgical populations involving bone instrumentation, for example sternotomy patients.

The decision to use lidocaine 5% plaster in this setting followed extensive consultation with the Trust pain team. The cohort of patients who will predominantly benefit from pain management with lidocaine 5% plaster are the IM nail patients, which is a complex surgical procedure that causes significant local trauma and pain. The other cohorts proposed for treatment with lidocaine plaster are IM nail patients who experience adverse effects from opioids or in whom opioid doses cannot be increased, due to adverse effects such as delirium. In practice, lidocaine 5% plaster has been

initiated in each patient following pain team input, with observed reductions in pain scores, opioid dose tapering, and improved rehabilitation outcomes.

A query was raised regarding the internal Trust audit carried out in 2024 where lidocaine 5% plaster was used in this setting for 14 patients and whether lidocaine 5% plaster has been used in more than 14 patients. The applicant confirmed, over the past year, of the 320 patients treated for NOF fractures, lidocaine 5% plasters has been used in 28 patients.

A comment was raised regarding the risk of lidocaine 5% plaster in this setting being transferred to primary care despite the proposed Red RAG category. It was explained that in line with national guidance, lidocaine 5% patches forms part of the LPP products and are not recommended for prescribing in primary care and that these plasters currently represent one of the highest spend LPP products for SEL. A key concern was the potential for lidocaine 5% plasters to be used beyond the recommended five-day period, with patients discharged on treatment and subsequently requesting ongoing prescriptions from their GP. The applicant clarified that lidocaine 5% plasters are strictly for in-hospital use, limited to a maximum of five days as part of a multimodal pain strategy to reduce opioid use. Patients are informed that treatment will not continue post-discharge, and no cases of prescribing post discharge have occurred.

Clarification was sought regarding patients who received lidocaine 5% plasters in hospital and began to experience pain again after discharge and how the GP should manage such patients, especially if opioids are not recommended. The applicant explained although non-steroidal anti-inflammatory drugs (NSAIDs) are avoided immediately post-op due to concerns around bone healing, once wounds have healed, and depending on patient-specific comorbidities, NSAIDs (topical or systemic) may be considered where appropriate. Clear discharge guidance will be provided to GPs.

A comment was raised regarding the pain mechanism in hip fracture patients which is different from other post-operative pain scenarios, particularly those involving more superficial pain generators. As such, extrapolating data from other surgical settings to this patient group without robust supporting evidence should be cautioned.

Clarification regarding the criteria for use was requested and whether the use of lidocaine 5% plaster is intended only for patients with an IM nail who also could not tolerate increases in opioid dose and were experiencing side effects or whether these are three separate patient cohorts. The applicant clarified that while all IM nail patients tend to have the highest pain scores, not all would be appropriate for lidocaine 5% plasters. The proposed approach would aim to use lidocaine 5% plasters in IM nail patients who are older and frail and therefore more likely to suffer from opioid-related side effects.

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

Committee members discussed the application and members acknowledged currently there is a lack of sufficient published evidence to support the use of lidocaine 5% plaster this setting. However, Committee members also appreciated the experience to date of using lidocaine 5% plaster in this patient cohort locally. Committee members agreed by consensus to defer the decision on whether to approve use of lidocaine 5% plaster this setting. Members requested the submission of additional supporting data collated by the GSTT ortho-geriatric team be presented to the committee at a future IMOC meeting for review.

ACTION: Supporting data collated by the GSTT ortho-geriatric team for the use of lidocaine 5% plaster in this setting to be presented at a future IMOC meeting

8. Formulary request to include tocofersolan (Vedrop®) for children and young people with severe cholestasis not responding to alpha tocopherol acetate as Amber 2

The applicant was in attendance to present a request for paediatric formulary inclusion of tocofersolan (Vedrop®), a licensed vitamin E supplement for children with congenital or hereditary

chronic cholestasis whose vitamin E levels remain sub-therapeutic despite high-dose oral alpha-tocopherol or intramuscular (IM) vitamin E supplementation. Children with cholestasis are at high risk of fat-soluble vitamin deficiencies, and current treatments can require large liquid volumes, which are challenging for younger children. Vedrop® is a water-soluble, more bioavailable form of alpha-tocopherol, allowing easier administration in smaller volumes and potential cost savings. It was agreed that the brand name Vedrop® would be specified in clinic letters to avoid prescribing confusion. From a cost perspective this formulary request is within the financial threshold delegated to the committee. The use of Vedrop® is more cost effective in comparison to the use of high-dose oral alpha-tocopherol and IM vitamin E injections, therefore there is a potential saving with the use of Vedrop®.

The committee agreed by consensus to include tocofersolan (Vedrop®) in the paediatric formulary as Amber 2 for children and young people with severe cholestasis unresponsive to alpha-tocopherol acetate.

ACTION: Tocofersolan (Vedrop®) in this setting as Amber 2 to be added to the paediatric joint medicines formulary

9. Updated Inflammatory Bowel Disease (IBD) pathways, cost tool, and associated formulary request

- **Proposal for subcutaneous (SC) infliximab (Remsima®) dose escalation in Crohn's disease (CD) - off-label**

The Specialist Pharmacist for Gastroenterology was in attendance to present this item which has been updated and approved via the IBD sub-group. The main updates to the IBD treatment pathway include the following:

- Move from 2nd line to 1st line for estrasimod in the management of ulcerative colitis (UC) in line with NICE Technology Appraisal (TA) 956 and the addition of guselkumab for the management of UC in line with NICE TA 194
- Addition of mirikizumab (NICE TA 1080) and guselkumab (NICE TA 1095) in line with NICE for the management of Crohn's disease (CD)

The IBD pathway cost tool has also been updated to include the new NICE TA approved treatment options and ustekinumab subcutaneous (SC) pen preparation. In line with the NICE resource impact statement for guselkumab in UC and guselkumab and mirikizumab in CD, these treatments are not anticipated to be a significant resource impact as they are a further treatment options for the patient cohorts they cover and the cost is likely to be a substitution. The specialists on the IBD subgroup agree with the NICE resource impact estimations.

The proposal for dose escalation of SC infliximab (Remsima®) in patients with CD (off-label) is intended for patients who were primary responders to IV or SC infliximab at week 10 but experience a loss of response to infliximab after week 22 of treatment. The dose escalation is from infliximab SC 120mg 2 weekly to 240mg 2 weekly or 120mg weekly. Dose escalated infliximab provides a cost-effective treatment option for this patient cohort who would otherwise be switched to an alternative advanced therapy which may be more costly. In the LIBERTY-CD trial, patients receiving SC infliximab 240mg bi-weekly after a loss of response at 22 weeks demonstrated a 61.8% response recovery rate by week 54, highlighting the potential efficacy of this proposal. The inclusion criteria, monitoring and safety considerations were detailed within the agenda paperwork.

From a cost perspective, this proposal is within the financial threshold delegated to the committee. The use of SC infliximab in this setting will be monitored through the IBD subgroup.

Committee members approved the following by consensus:

- updated IBD pathways and cost tool
- Dose escalated subcutaneous infliximab (Remsima®) for the management of Crohn's disease (off-label)

10. Update on progress with IMOC workplan 25-26 quarter 1 & 2

The leads presented this item and noted there has been good progress in the areas noted within the workplan. The review of existing IMOC guidelines, treatment pathways and resources are underway. A comprehensive stocktake of current existing IMOC guidelines, treatment pathways and resources has been completed, and a list of these resources has been shared with relevant leads to determine their future status. Each resource is being considered for retention, review, or retirement. A summary of the proposed plan for each resource will be presented at a future committee meeting. Work is also ongoing to develop digital solutions to enhance meeting efficiency and guideline consultations.

Members noted the update.

11. Standing Items:

- Formulary submissions tracker

Noted.

- *NICE Technology Appraisal (TA) Guidance Summary – Integrated Care Board 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 1100 - Mirabegron for treating neurogenic detrusor overactivity in people 3 to 17 years (terminated appraisal), the committee agreed a 'non-formulary - not recommended for prescribing' category which will need to be reflected in the paediatric joint medicine's formulary. **ACTION: Mirabegron for treating neurogenic detrusor overactivity in people 3 to 17 years to be added to the paediatric joint formulary as non-formulary – not recommended for prescribing**

- *For information and noting only:*
  - World Antimicrobial Resistance Awareness Week (WAAW) – implementation plan
  - Pan-London "Red Amber Green" (RAG) definitions – implementation plan for SEL
  - Adult and paediatric formulary updates September 2025

The above were noted by committee members.

12. Specialist primary care weight management service pilot for tirzepatide (Mounjaro®) in adults

The author was in attendance to present this item, outlining a new specialist primary care weight management service pilot for the use of tirzepatide (Mounjaro®) in adults for weight management. NICE TA 1026 recommends tirzepatide as an option for managing overweight and obesity, alongside a reduced-calorie diet and increased physical activity for patients with a body mass index (BMI) above 35 kg/m² (adjusted for ethnicity where relevant), and at least one weight-related comorbidity. Although NICE recommends use in primary care and specialist weight management services (SWMS), the necessary infrastructure is not yet in place across most NHS health care systems.

Across SEL, SWMS - Tier 3 and Tier 4 services are already engaged in a phased rollout of tirzepatide in this setting. The primary care based weight management service pilot is due to launch in November 2025, delivered by local GP federations. This service will initially treat patients from the NHS England-defined Cohort 1. Currently, the use of tirzepatide in patient cohort 1 is included within the SEL adult JMF as Amber 2, initiation is only recommended by SWMS with prescribing continued in primary care after a minimum of 3 months of prescribing by the SWMS. An information sheet was approved earlier in the year to support this process.

Committee members were requested to consider an update to the Amber 2 criteria for tirzepatide in this setting to include the Lambeth, Southwark, and Lewisham specialist primary care weight management service pilot. The pilot primary care service will manage patients for 12 months, including initiation of tirzepatide, dose titration, and annual review, before patients are discharged to their GP for on-going prescribing and review. Committee members noted there is no change to the

financial impact for the use of tirzepatide in this setting which were presented at the March IMOC meeting and escalated to the Executive committee for information in April 2025.

A comment was raised regarding whether the 12 months of tirzepatide prescribing by the specialist primary care weight management service pilot refers to the pilot operating for 12 months or if prescribing from the service will be for 12 months. The presenter clarified "12 months" refers to 12 months of treatment for each individual patient and not the total duration of the pilot. In response to a query about patients in long stay forensic settings, the presenter confirmed engagement has begun with clinicians from forensic services to explore solutions, although challenges remain due to variable access to wraparound care and differences in funding streams.

Committee members agreed by consensus an update to the SEL adult JMF tirzepatide amber 2 formulary entry to include the initiation of tirzepatide for weight management by the pilot specialist primary care services in Lambeth, Lewisham, and Southwark boroughs.

ACTION: SEL adult JMF tirzepatide amber 2 formulary entry to be updated to include the pilot specialist primary care services in Lambeth, Lewisham, and Southwark boroughs

13. Local response to diabetes related product discontinuations:

- **Updated GLP-1 analogue pathway for type 2 diabetes**

The authors were in attendance to present updates to the GLP-1 pathway for type 2 diabetes, reflecting the new Rybelsus® (oral semaglutide) formulation, a more bioavailable formulation which replaces the original 3 mg, 7 mg, and 14 mg tablets with 1.5 mg, 4 mg, and 9 mg doses without a change in cost. The new formulation is available to prescribe since September 2025 and the original formulation is being phased out over the next four to six months. During this time, both formulations may co-exist, creating potential dosing risks; a communication plan has been implemented to mitigate these.

The pathway has also been updated to reflect the discontinuation of the liraglutide brands Saxenda® and Victoza® and now notes that liraglutide is available as a branded generic. Committee members were requested to consider an update to the SEL adult JMF to include liraglutide generically, noting branded generics are available for the management of type 2 diabetes (T2DM) and weight management. Committee members noted that exenatide extended release (Bydureon®) has also recently been discontinued and requested the GLP-1 pathway is updated to reflect this too.

A comment was raised on the proposed formulary wording for branded generic liraglutide, suggesting this is aligned to the wording for biosimilar products, which the presenter confirmed was suitable. In response to a query about potential savings from branded generic formulations of liraglutide, the presenter confirmed that branded generic formulations offer a 30–40% cost reduction compared with Saxenda® and Victoza®, though overall financial impact is limited due to the low patient number prescribed liraglutide.

Committee members approved the formulary inclusion of generic liraglutide for the management of T2DM and weight management and the updated GLP-1 pathway by consensus pending updates to the pathway in line with the discussion.

ACTION: GLP-1 pathway to be updated in line with discussions and progressed for ratification via IMOC Chair's action
ACTION: Branded liraglutide for the management of T2DM (Victoza®) and weight management (Saxenda®) to be updated within the SEL adult JMF as generic liraglutide

- **Formulary inclusion of FreeStyle® Libre 3 plus (FreeStyle® Libre 3 discontinuation) for type 1 diabetes (adults and paediatrics)**

The applicant was in attendance to present this item, which has been approved via the diabetes sub-group and local paediatric diabetes teams. The FreeStyle® Libre 3 (FSL3) device will be

discontinued by December 2025 and replaced by FreeStyle® Libre 3 Plus (FSL3 Plus). The new sensor offers a 15-day wear time (previously 14 days) and is licensed for use in children aged 2 years and older (previously 4 years). The presenter confirmed that both the adult and paediatric diabetes teams had reviewed the transition plan. The FSL3 Plus is available through the NHS Supply Chain and via FP10 prescriptions, with no price differential.

Committee members noted the guideline for continuous glucose monitoring (CGM) in children and young people (CYP) living with type 1 diabetes (T1DM) is still underway. In line with this FSL3 is not currently in the SEL paediatric joint medicines formulary, therefore FSL3 plus cannot be added to the SEL paediatric joint medicines formulary until the approval of the CGM guidance in CYP living with T1DM.

The implementation plan will mirror previous CGM transitions, involving tools for identifying patients, communication with pharmacies, and letters to patients and providers. Committee members noted the template patient letters (adults and paediatrics) within the agenda pack for approval and the community pharmacy discontinuation memo for information.

Committee members approved by consensus the template patient letters for adults and paediatrics to support the FreeStyle® Libre 3 discontinuation and the formulary inclusion of FreeStyle® Libre 3 plus for adults.

ACTION: FreeStyle Libre® 3 to be replaced with FreeStyle Libre® 3 plus in the SEL adult JMF

14. Any other business

This is the last meeting for the Senior Pharmacist supporting the committee before they begin their maternity leave. Committee members offered their thanks and appreciation and wished them a happy maternity leave.

IMOC dates for the next 3 months

Date	Time	Venue
Thursday 20th November 2025	2pm - 4.30pm	MS Teams
Thursday 18th December 2025	2pm - 4.30pm	Hybrid (MS Teams/in person)
Thursday 15th January 2026	2pm – 4:30pm	MS Teams