South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
17th July 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 noted 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. No conflicts were raised by members.

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. Formulary request for methenamine hippurate for the treatment of recurrent urinary tract infection (UTI) and associated costings

The applicants were in attendance to present this item which is a request on behalf of the SEL Forum for Antimicrobial Stewardship (SEL FAS). The request is to amend the existing formulary inclusion of methenamine hippurate for the treatment of recurrent urinary tract infection (UTI) for adults and paediatrics in line with the updated National Institute for Health and Care Excellence (NICE) guideline (NG112) - urinary tract infection (recurrent) - antimicrobial prescribing as follows:

- Amendment to use in adults (Green RAG category) - an alternative to daily antibiotic prophylaxis for recurrent UTI in non-pregnant women, trans men, and non-binary people with a female urinary system if they meet all the following criteria:
  - they are not pregnant
  - any current UTI has been adequately treated
  - they have recurrent UTI that has not been adequately improved by behavioural and personal hygiene measures, vaginal oestrogen, or single-dose antibiotic prophylaxis

- New Inclusion of the following cohorts as Amber 1 RAG category, where NG112 recommends specialist advice is sought if considering methenamine hippurate as an alternative to daily antibiotic prophylaxis for recurrent UTI:
  - during pregnancy
  - in people with recurrent upper UTI or complicated lower UTI
  - in men, trans women, and non-binary people with a male genitourinary system
  - in children and young people (6 years old and over)

Committee members were also requested to consider the recategorisation from Red *(hospital only)* to Amber 1 *(initiation on advice of a specialist)* for use in paediatrics. Use in paediatrics will be in a very small patient cohort aged 6 years an over (in line with the licence) through the Evelina bladder services, general paediatrics, urology, or nephrology services.

The proposed updates to the recurrent UTI section (adults and paediatrics) of the primary care antimicrobial guideline in line with the use of methenamine hippurate in this setting was also included within the agenda pack for approval by committee members.
From a cost impact perspective this formulary request is within the financial threshold delegated to the committee. As methenamine hippurate has been included in the adult joint medicines formulary (JMF) for several years, there is an existing baseline spend in SEL and SEL is one of the higher end prescribers when compared nationally. The gap between the NICE resource impact estimated cost

and primary care spend for methenamine hippurate in 2024/2025 likely reflects the estimated cost impact for methenamine hippurate in this setting for SEL adults.

A comment was raised in relation to SEL primary care prescribing of methenamine being the third highest across England and in line with this, it would be useful for the primary care prescribing of methenamine to be audited via SELFAS. The presenter confirmed this would be possible and will be fed back at the next SELFAS meeting.

GP committee members queried the Amber 1 categorisation of methenamine hippurate in paediatrics. As this patient cohort is small and predominantly diagnosed by specialist teams, an Amber 2 categorisation (specialist initiation) would be more appropriate.

Committee members approved by consensus the amended formulary inclusion of methenamine hippurate as an alternative to daily antibiotic prophylaxis in the following patient cohorts in line with NICE guideline - NG112:

- non-pregnant women, trans men, and non-binary people with a female urinary system as Green
- during pregnancy, in people with recurrent upper UTI or complicated lower UTI, in men, trans women and non-binary people with a male genitourinary system as Amber 1
- in children and young people (6 years old and over) as Amber 2

Committee members also approved by consensus the updated recurrent UTI section (adults and paediatric) of the primary care antimicrobial guideline pending amendments to the in line with discussions.

ACTION: Recurrent UTI section (adults) of the primary care antimicrobial guideline to be updated in line with discussions and progressed for IMOC Chair's ratification
ACTION: SEL JMF to be updated for the use of methenamine hippurate for the management of recurrent UTI as Green and Amber 1
ACTION: SEL joint paediatric formulary to be updated for the use of methenamine hippurate for the management of recurrent UTI as Amber 2

5. **COVID-19 medicines update, outcomes and monitoring framework and cost modelling for COVID-19 treatments following NICE Technology Appraisals (TA)'s:**
    - **New NICE TA: molnupiravir for treating COVID-19 (TA 1056)**
    - **Updated NICE TA: Nirmatrelvir plus ritonavir (Paxlovid®), sotrovimab and tocilizumab for treating COVID-19 (TA 878)**

The author was in attendance to present this item. This is an update on behalf of SEL FAS in relation to COVID-19 medicines and a request to approve the updated outcomes and monitoring framework for COVID-19 medicines.

NICE Technology Appraisal (NICE TA 878) for the use of Paxlovid®, sotrovimab and tocilizumab for treating COVID-19 has been recently updated following an initial partial review of the guideline in March 2024 in line with the confidential pricing agreement offered by the manufacturer to the NHS. In May 2025, the manufacturer withdrew the confidential pricing agreement and reverted to the list price. In view of this, NICE TA 878 no longer considers Paxlovid®, sotrovimab and tocilizumab for treating COVID-19 to be cost effective for the cohort of patients noted in the partial review of NICE TA 878.

A new NICE TA (1056) has been recently published for molnupiravir for treating mild to moderate COVID-19 which replaces the previous conditional recommendation. Molnupiravir remains as 3rd line treatment option therefore no change in practice or usage is anticipated. It is not anticipated that the use of molnupiravir in this setting will have a significant resource impact as molnupiravir is a further treatment option and the overall cost of treatment will be similar for this population.
As of July 2025, the Department of Health and Social Care (DHSC) free of charge (FOC) stock has expired for molnupiravir, Paxlovid® and remdesivir, therefore creating a potential cost pressure for the local health system for 2025/26. There is a DHSC FOC stock expiry extension until early 2026 for sotrovimab, however availability beyond this period is currently unclear.

In line with the new and updated NICE TAs for COVID-19 medicines and updates to the DHSC FOC stock, the local COVID-19 medicines outcomes and monitoring framework for 2025/26 has been updated and approved via SEL FAS. The monitoring of COVID-19 treatments for both non-hospitalised and hospitalised patients transitioned from NHS England (NHSE) to Integrated Care Boards (ICBs) as of April 2023. The outcomes and monitoring framework enables the regular assessment and usage of COVID-19 high-cost drugs provided to hospitalised patients and non-hospitalised patients via the covid medicines delivery unit (CMDU).

Committee members noted that the outcomes and monitoring framework reflects the recommendations for COVID-19 treatments in line with legacy NHSE commissioning policies. In line with this, the outcomes and monitoring framework notes that patients can be treated up to 7 days from onset of symptoms. Although this is in line with the legacy NHSE commissioning policies, it is outside of the licence for the medicines and therefore outside NICE guidance, as the licence covers treatment within 5 days of symptom onset. The presenter explained that accessing COVID-19 treatment within this five-day window may pose challenges for both non-hospitalised patients and those hospitalised later. Other CMDUs in London also allow treatment within 7 days of symptom onset and continuing access in this timeframe was supported by SEL FAS.

From a cost impact perspective, forecasting has been estimated from local prescribing data and the NICE resource impact report, with a 10% to 20% increase in spend on COVID-19 medicines year on year applied. Based on the total spend on COVID-19 medicines in 2024/25 and the forecasted spend on COVID-19 medicines for 2025/26, the revised estimated cost impact associated with the COVID-19 treatments is above the financial threshold delegated to the committee. In line with the Terms of Reference for the committee, the cost modelling will need to be escalated to the Executive Committee for information. It was noted that this has also been highlighted through the horizon scanning process. Committee members noted, any significant increase in the number of COVID-19 cases would result in a larger cost impact on COVID-19 treatments. However, this cannot be accurately predicted due to the nature of the pandemic and changing viral strains.

A comment was raised in relation to the indicator measuring the impact on overall COVID-19 medicines cost to ensure value for money and how this will be measured. It was clarified that this is linked to the high-cost drugs report produced by the SEL ICB Business Intelligence team which provides data on the high-cost drugs usage by Trusts.

Committee members noted the update on COVID-19 medicines and approved by consensus the updated outcomes and monitoring framework for COVID-19 medicines used in non-hospitalised and hospitalised patients.

ACTION: Revised cost impact for COVID-19 medicines to be escalated to the Executive Committee for information

6. Formulary request for Trurapi® (biosimilar insulin aspart) for the management of adults with diabetes

The applicants were in attendance to present this item on behalf of the of the diabetes sub-group. This is a request for the formulary inclusion of Trurapi® (biosimilar insulin aspart) as the first line insulin aspart 100 unit/mL product when initiating insulin aspart treatment in adults (18 years and over) with a Green RAG category, in line with the originator product on the adult JMF NovoRapid®.

Trurapi® is the first biosimilar aspart insulin in the UK which launched in 2021 and has been found to be clinically similar in trials to the originator product NovoRapid®, with comparable safety, tolerability, and incidence of hypoglycaemia with identical licensed indications.

Due to the number of shortages and/or discontinuations of insulins and glucose lowering therapies, a phased introduction for Trurapi® initiations is being proposed by the diabetes sub-group as follows:

- New patients suitable for insulin aspart in line with NICE guidance

- Clinicians titrating a patient's NovoRapid® dose due to inadequate glycaemic control (while maintaining consideration of user ability and satisfaction with a device)

Further phasing for Trurapi® initiations will be discussed and agreed by the diabetes sub-group.

The GSTT Formulary Pharmacist provided a brief overview of the evidence to support the formulary inclusion request for Trurapi®. A pharmacokinetic study involving 30 male patients with type 1 diabetes demonstrated that Trurapi® exhibited comparable pharmacokinetics and pharmacodynamics (PK/PD) to NovoRapid®. This finding was further validated by a similar study in 40 Japanese patients, confirming no significant differences between Trurapi® and NovoRapid®.

In relation to glycaemic control, a non-inferiority randomised phase three trial with 597 patients with type 1 or type 2 diabetes treated with Trurapi® or NovoRapid® in combination with glargine. The trial demonstrated similar changes in HbA1c between both treatment groups over 26 weeks meeting the criteria for non-inferiority for Trurapi® to NovoRapid®. Consequently, the European Medicines Agency (EMA) recognised Trurapi® as a biosimilar to NovoRapid®, noting similar immunogenicity risks without increased development of anti-insulin antibodies.

From a cost impact perspective, the cost impact of this formulary request is within the financial threshold delegated to the committee and is expected to release some savings.

A query was raised regarding the amber 2 categorisation of Abasaglar® (biosimilar insulin glargine) and the rationale for recommending a green categorisation for Trurapi®. The presenter clarified the proposed Green categorisation Trurapi® is in line with the current prescribing practice for NovoRapid®. Although NovoRapid® is uncategorised in the adult JMF, NovoRapid® is commonly initiated in both primary care as well as in secondary care settings. The Amber 2 categorisation for insulins such as Abasaglar® is due to the complexity of the insulin regimens and initiation in high-risk patient cohorts

GP committee members raised concerns in relation to the proposed Green category due to the risks associated with prescribing insulin alongside the current arrangements in many GP practices where the initiation of insulin is usually carried out by health care professionals with a specialist interest in diabetes. In line with this, majority of GP committee members suggested an Amber 1 categorisation would be more appropriate for both Trurapi® and NovoRapid®.

In response to views shared by most GP committee members, the presenter explained an Amber 1 categorisation may have an impact on existing primary care health care professionals who initiate NovoRapid®; they may interpret Amber 1 as they are no longer permitted to initiate NovoRapid® (or Trurapi®) in primary care unless they receive advice to do so from a secondary care specialist. This may inadvertently delay insulin initiation in people living with type 2 diabetes (T2DM). There is a marked increase in hospital admissions due to hyperglycaemia in people living with T2DM, emphasising the need for caution in implementing an Amber 1 categorisation which may deter established safe practices in primary care.

In relation to the formulary entry for NovoRapid® and Trurapi® it was suggested that if an Amber 1 category is approved, the formulary entry can be made clear that initiation can be carried out by a suitable specialist in primary care.

A query was raised in relation to the implementation plan across the local health system for Trurapi® and whether any communications will be made available. The presenter confirmed communications would be developed if approved and plans regarding local implementation will be discussed and agreed via the diabetes sub-group.

Committee members agreed that the desired Green RAG category would not be appropriate for the reasons discussed and did not approve the request. The committee approved by consensus the formulary inclusion of Trurapi® (biosimilar insulin aspart) for the management of adults with diabetes with a RAG category of Amber 1. The committee agreed by consensus to also categorise NovoRapid® as Amber 1.

ACTION: Trurapi® for the management of adults with diabetes to be added to the SEL adult JMF as Amber 1 with information on the agreed phased approach and patient cohort. NovoRapid® to be added to SEL adult JMF as Amber 1

7. Updated Clinical Effectiveness South East London (CESEL) guide for chronic kidney disease (CKD): approval of the updated medicines content

The authors were in attendance to present this item, which is being presented to the IMOC for approval of the medicine's elements. The CESEL CKD guide has been updated to align with the London Kidney Network (LKN) CKD optimisation pathways, NICE TAs 942 and 1075 (empagliflozin and dapagliflozin respectively) for treating CKD. The recently updated NICE TA 1075 for dapagliflozin now aligns to the criteria for use of empagliflozin for CKD. The presenter outlined the work to update the guide which included extensive collaboration between CKD specialists and primary care professionals, aimed at addressing the low adoption of sodium-glucose co-transporter-2 inhibitors (SGLT2i) inhibitors in SEL.

The guide has been through IMOC consultation and the main updates to the guides include:

- Removal of checking urine albumin to creatine ratio (ACR) in patients with T2DM as a step before starting angiotensin-converting enzyme inhibitors (ACE-I) or angiotensin II receptor blockers (ARB)
- Addition of reviewing patients' renal function (eGFR) for suitable treatment options in patients with CKD without diabetes
- Addition of empagliflozin in line with NICE TA 942 and update to existing information on dapagliflozin initiation in line with updated NICE TA 1075 for people with CKD (existing patients on canagliflozin in this setting may remain on treatment but new initiations are not recommended)
- New section added which details the criteria for initiating SGLT2i's in people with CKD

The removal of checking urine ACR as a step before stating ACE-I/ARB in patients with T2DM follows the recommendations as per the LKN CKD optimisation pathways and NICE TA guidance for dapagliflozin or empagliflozin which differs to the recommendations within the NICE guideline on CKD assessment and management (NG203). This change in practice in SEL is expected to double the T2DM patient cohort eligible for treatment with a SGLT2i for the management of CKD. Currently, SEL is the second lowest prescriber of SGLT2i nationally in all indications, demonstrating the importance of implementing the updated guide widely and appropriately across SEL.

From a cost impact perspective, the cost impact of implementing updated NICE TA 1075 – dapagliflozin in CKD is within the financial threshold delegated to the committee. In line with the NICE resource impact, it is not anticipated that the use of dapagliflozin in this setting will have a significant resource impact as dapagliflozin is a further treatment option alongside empagliflozin and the overall cost of treatment will be similar for this population.

A request was raised relating to the addition of a statement clarifying that canagliflozin is for patients already established on treatment and not recommended for new initiations. A query was raised in relation to the inclusion of overprescribing and/or deprescribing considerations to the guide. The presenter explained that development of a multi-long term conditions (LTC) CESEL guide, which will include polypharmacy/overprescribing elements, is underway. However, the timescales for this guide are currently unconfirmed. Once available, the CESEL multi LTC guide will be linked within the CESEL CKD guide.

Committee members approved by consensus the updated medicines content of the CESEL CKD guide, including the RAG categorisation of empagliflozin as Green, pending amendments to the guide in line with the discussion. Dapagliflozin remains with the existing RAG category of Green.

ACTIONS: CESEL CKD guide to be updated in line with discussions and progressed for IMOC Chair's ratification

8. i. Guideline for the pharmacological management of Postural Tachycardia Syndrome (POTs)

The authors were in attendance to present this item. This guideline has been developed following the formulary application for pyridostigmine for the management of POTS presented at IMOC in July 2024. At the time, committee members were minded to agree the requested Amber 3 categorisation for pyridostigmine but required further clarity regarding areas such as primary care monitoring, blood test requirements, ongoing review of patients and further details on the role of GPs under the shared care arrangements. This guideline aims to addresses these areas

The guideline has been through IMOC consultation and approval via the CVD sub-group. Post IMOC consultation the CVD sub-group conducted a review of the existing ivabradine and midodrine prescribing guidance, transfer of prescribing responsibility and notification of initiation in line with the amber 3 arrangements and agreed the following:

- Retirement of the notification of initiation forms for ivabradine and midodrine
- Retirement of the ivabradine and midodrine prescribing guidance. However, relevant information will be included within the POTS guideline
- Combined transfer of prescribing responsibility document for ivabradine, midodrine and pyridostigmine with a view of retiring the separate ivabradine and midodrine transfer of prescribing responsibility documents

Through the review of the midodrine prescribing guidance, it was identified that the document includes dosing information for the use of midodrine in orthostatic hypertension. As this is not covered in the POTS guideline, committee members were requested to approve the inclusion of this information within the SEL adult JMF.

ii. Formulary recommendations

- New: Pyridostigmine for the treatment of POTS
- Updated (032): Midodrine for the treatment of POTS or Inappropriate Sinus Tachycardia (IST)
- Updated (033): Ivabradine for the treatment of POTS or IST

A new formulary recommendation has been drafted for the use of pyridostigmine for the treatment of POTS in line with the guideline developed to support the approval of the pyridostigmine formulary application presented at the July 2024 IMOC meeting. The formulary recommendations for the use of midodrine and ivabradine for the management of POTS or Inappropriate Sinus Tachycardia (IST) has also been updated in line with the development of the POTS guideline. The new and updated formulary recommendations were shared with the IMOC virtual Triage Panel with no comments received.

A comment was raised requesting the addition of information relating to deprescribing and/or stopping treatment, especially as multiple treatments can be used for the management of POTS. The presenter confirmed this can be included within the guideline.

A query was raised regarding whether there is a maximum and common maintenance dose for the use of propranolol in this setting. The presenter clarified the dose of propranolol in this setting differs for each patient and depends on how well patients tolerate propranolol. Majority of patients reach doses of 20mg – 30mg daily but the maximum dose would not exceed 160mg, but doses are rarely titrated to this maximum dose.

It was queried whether the use of pyridostigmine following treatment with propranolol in patients with POTS who have a high BP, is as add on treatment in this setting. The presenter explained that, in line with the guideline, if there is no benefit after six weeks of treatment with propranolol, it should be stopped before trialling pyridostigmine. If there is some benefit with propranolol but the patient is still symptomatic, then pyridostigmine can be added as the next line of therapy.

GP committee members explained that POTS is a complex disease which is very rarely diagnosed in primary care. In line with this, the treatments noted in the primary care section of the treatment pathway as RAG category Green (sodium chloride, propranolol, and fludrocortisone) are unlikely to be started by GPs prior to a firm diagnosis by specialist cardiology teams.

In response to the views shared by the GP committee members, the presenter explained the Royal College of GPs has acknowledged the importance of POTS management in primary care in recent guidelines, and there is currently a national initiative aimed at establishing standardised primary and secondary care guidelines for the management of POTS. While some patients are being diagnosed for POTS in primary care, a notable number of patients are still diagnosed in secondary care.

A query was raised in relation to whether patients are usually already on treatments such as propranolol and fludrocortisone when they are seen in secondary care for specialist input. The presenter clarified many patients are often on propranolol when they are reviewed in secondary care as many patients with POTS often also experience migraine and/or anxiety which propranolol is also prescribed for. However, treatments such as sodium chloride and fludrocortisone are often initiated in primary care following specialist recommendation.

In view of the comments raised by GP committee members, in relation to the diagnosis of POTS predominantly occurring in secondary care, committee members agreed by consensus a review of the primary care section of the treatment pathway alongside the proposed Green categorisation for sodium chloride, propranolol and fludrocortisone should be reviewed by the CVD sub-group.

Committee members approved the following by consensus:

- Guideline for the pharmacological management of POTS pending amendments to the guideline in line with the discussions
- Retirement of the ivabradine and midodrine notification of initiation forms
- Retirement of the ivabradine and midodrine prescribing guidance documents
- Combined transfer of prescribing responsibility document for ivabradine, midodrine and pyridostigmine and retirement of the separate ivabradine and midodrine transfer of prescribing responsibility documents
- Addition of dosing information for the use of midodrine in orthostatic hypertension to the local adult JMF
- New formulary recommendation - pyridostigmine for the treatment of POTS
- Updated formulary recommendations - midodrine and ivabradine for the treatment of POTS and IST

ACTION: Guideline for the pharmacological management of POTS to be updated in line with discussions and progressed for IMOC Chair's ratification
ACTION: Pyridostigmine as Amber 3 for the management of POTS to be added to the SEL adult JMF
ACTION: Categorisation of sodium chloride, propranolol, and fludrocortisone to be agreed by the CVD sub-group and progressed for IMOC Chair's ratification
ACTION: Categorisation of sodium chloride, propranolol, and fludrocortisone to be added to the SEL adult JMF following IMOC Chair's ratification
ACTION: Dosing information for the use of midodrine in orthostatic hypertension to be added to the SEL adult JMF

9. Request to extend Pylera® (bismuth140mg/metronidazole 125mg/tetracycline 125mg) duration of use to 14 days for refractory cases of H Pylori (off-label) as Amber 1

The Formulary Pharmacist presented this item. Pylera® was approved at the February 2025 IMOC meeting for inclusion within the local adult JMF as an alternative to Pepto-Bismol® for bismuth regimens used for the management of *H pylori* due to the long-term stock issues with Pepto-Bismol®. The formulary entry for Pepto-Bismol® includes a recommended treatment duration of 7 – 14 days for the management of *H pylori* infection. As Pylera® is the only licensed product on the SEL

adult JMF which contains bismuth, infectious disease and gastroenterology specialists would like to also use Pylera® for a duration of 14 days for the management for refractory H pylori infection.

In line with NICE guidance, the recommended treatment duration of bismuth regimens for the treatment of H pylori is 7 days and the licensed treatment duration is 10 days. The treatment duration of 14 days will only be used in this setting for patients as third line treatment who fail two previous *H pylori* treatment courses. Committee members noted that the use of bismuth for 14 days is established practice, and this request for Pylera aligns to the adult JMF entry for Pepto-Bismol®. This request has been discussed by SEL FAS who are in support of the formulary request but requested the definition of refractory (two previously failed treatment courses) is made clear on the adult JMF.

A comment was raised in relation to the adult JMF entry for Pylera® which should include the defined criteria of refractory *H pylori* and an update to the *H pylori* section of the primary care antimicrobial guideline to reflect the extended duration of treatment with Pylera® in refractory cases of H pylori.

Committee members approved by consensus the request to extend the duration of use for Pylera® from 7 days to 14 days (off-label) in refractory cases of *H pylori* infection as Amber 1.

ACTION: The treatment duration of 14 days for Pylera® (off-label) to be added to the SEL JMF as Amber 1 with a definition of refractory included
ACTION: The H pylori section of the primary care antimicrobial guideline to be updated to include the treatment duration of 14 days for Pylera® as Amber 1 and progressed for IMOC Chair's ratification

10. Paediatric formulary "Red, Amber, Green" RAG rating review:
- **Phase 5 - medicines used in pain and general paediatrics**

The author presented this item, which aims to update the formulary RAG categories for paediatric medicines used in pain and general paediatrics in line with their actual use in practice. This is part of a larger ongoing project where a full review is being undertaken to consider the appropriate RAG category for a medicine in paediatrics considering the different indications and specialties it may be used in and liaising with the relevant teams across SEL hospital trusts. This process is not being used to consider down recategorising of Red or Amber 3 medicines, which will remain the same. There are also existing Green, Amber 1 and Amber 2 medicines which are appropriate and do not require a change in RAG category.

The table provided within the agenda pack summarises the drug class, the indications, and the current and proposed RAG categories for phase 5 - medicines used in pain and general paediatrics. The majority of the medications reviewed are being proposed to move from Green, Amber 1, or Amber 2. In general, medications within the same class are assigned the same RAG category, however, there are some instances where 2nd or 3rd line agents and or those indications with little experience or use in paediatrics may be given a higher RAG category meaning a greater amount of specialty input on initiation.

A comment was raised in relation to the Amber 2 categorisation of amitriptyline for migraine prophylaxis in paediatrics and whether the proposed recategorisation form Green to Amber 1 for the use of amitriptyline in neuropathic pain should be aligned. The presenter clarified that the patient cohort for the use of amitriptyline in neuropathic pain is small, and an Amber 1 category should be appropriate and deferred to views from GP committee members. GP committee members agreed with the proposed Amber 1 category.
Clarification was requested regarding the change in RAG categorisation for oromucosal midazolam and oral morphine from Green to Amber 1 and how this would impact their supply for the management of medical emergencies within a GP practice. The presenter clarified that the Amber 1 categorisation for oromucosal midazolam and oral morphine is for scenarios where repeat prescriptions are required following a diagnosis and does not apply to their use when stocked and accessed via the GP practice emergency medicines supply route.

Committee members approved by consensus the proposed changes to the RAG categories for paediatric medicines used in pain and general paediatrics.

ACTION: Paediatric formulary to be updated with approved RAG category changes for paediatric medicines used in pain and general paediatrics

- **Amendment to proposed RAG rating for intramuscular hydrocortisone**

At the February 2025 IMOC meeting an amendment to the RAG rating for intravenous hydrocortisone was approved which resulted in the injectable forms of hydrocortisone being recategorised from Green to Red for any indication and route. However, the specialist endocrine team raised a query regarding this recategorisation, highlighting that in paediatrics with adrenal sufficiency, who are maintained on oral hydrocortisone, they may require hydrocortisone injection for intramuscular (IM) emergency use. Historically prior to the recategorisation, GPs have been requested to prescribe IM hydrocortisone on the advice of the specialist endocrine team. In line with this, the specialist endocrine team are requesting a recategorisation of IM hydrocortisone from a RAG category of Red to Amber 2.

Committee members approved by consensus the request to amend the RAG rating for intramuscular hydrocortisone from Red to Amber 2.

ACTION: RAG rating for IM hydrocortisone to be updated from Red to Amber 2 in the paediatric formulary

- **Review of proposed RAG rating for domperidone**

Domperidone is currently categorised as Amber 2 within the local joint paediatric formulary, at the April 2025 IMOC meeting it was proposed domperidone remains as Amber 2 for the management of gastro-oesophageal reflux and gastric-stasis. However, a Red category was suggested by committee members due to the Medicines and Healthcare Regulatory Agency (MHRA) safety alert linked to the use of domperidone for the management of nausea and vomiting.

The proposed Red category for domperidone has been discussed with the specialist paediatric gastroenterology team and the team have concluded the Amber 2 categorisation is appropriate in this setting. Domperidone is no longer recommended as a treatment option for nausea and vomiting in the joint paediatric formulary and is used mainly in children with severe gastric stasis who tend to be under the care of the learning disability team. The 2014 MHRA safety alert advising on the risk of cardiac side effects with domperidone gives detail only on the use of domperidone in nausea and vomiting and does not acknowledge a risk associated with continued use in children with gastroesophageal reflux disease (GORD) and gastric stasis.

Patients, parents, or carers are made aware of the cardiac side effects associated with domperidone and the off-label use of domperidone in this setting when treatment is initiated. Patients, parents or carers are also signposted to resources for further information. As documented in the SEL joint paediatric formulary, a pre-treatment electrocardiogram (ECG) is performed prior to initiating domperidone, and a second ECG is carried out one week post initiation.

Committee members approved by consensus the request for domperidone to remain as Amber 2 for the management of GORD and gastric stasis.

11. Formulary entries for the following medicines used to treat cholestatic pruritus as Amber 2: bezafibrate, naltrexone, sertraline, rifampicin

The Formulary Pharmacist presented this item with support from a local Hepatology Consultant Pharmacist, who was in attendance. The formulary inclusion of bezafibrate, naltrexone, sertraline and rifampicin as Amber 2 and categorisation of colesevelam and colestyramine as Green in this setting was tentatively approved at the April 2025 IMOC meeting pending development of enhanced formulary entries to support prescribing. The applicant was requested to draft formulary entries

including clear information detailing starting criteria, stopping criteria or criteria for moving to the next treatment and the place in therapy.

The proposed formulary entries were provided within the agenda pack. The presenter clarified that the proposed formulary entry for colestyramine which notes colestyramine is off-label for the management of cholestatic pruritus requires updating to remove the off-label statement as colestyramine is licensed in this setting.

A query was raised in relation to the advice to switch patients with a creatinine clearance below 60 millilitres per minute from bezafibrate modified release tablets to immediate release tablets and if primary care clinicians will be expected to switch patients. The presenter clarified that the specialist team will switch patients, and this can be added to the proposed formulary entry for bezafibrate.

Committee members approved by consensus the formulary entries for the following medicines used to treat cholestatic pruritus:

- Bezafibrate, naltrexone, sertraline, rifampicin as Amber 2
- Colestyramine and colesevelam as Green

ACTION: Formulary entries for bezafibrate, naltrexone, sertraline, rifampicin as Amber 2 and colestyramine and colesevelam as Green used to treat cholestatic pruritus to be added to the SEL JMF

12. Standing Items

- Formulary submissions tracker

Noted.

- NICE Technology Appraisal (TA) Guidance Summary – ICS & 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 1066 - somapacitan for treating growth hormone deficiency in people 3 to 17 years the committee agreed an Amber 3 categorisation in line with existing growth hormone deficiency medicines on the paediatric formulary. A review of the shared care guideline for growth hormone in paediatrics will be required to incorporate somapacitan.

ACTION: Review of paediatric growth hormone shared care guideline to be progressed

- For information and noting:
  - FreeStyle Libre 2 discontinuation letters for adults and paediatrics were approved via the urgent Triage Panel process – noted by committee members.

13. Any other Business

Committee members were reminded that the August meeting is in hybrid.

IMOC dates for the next 3 months

Date	Time	Venue
Thursday 21st August 2025	2pm – 4:30pm	Hybrid in person/MS Teams
Thursday 18th September 2025	2pm – 4:30pm	MS Teams
Thursday 16 October 2025	2pm – 4:30pm	MS Teams