South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
21 November 2024 (Online via MS Teams)
Final Minutes

1. Welcome, introductions and apologies

The Chair welcomed attendees to the meeting. Apologies and observers were noted. 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.

3. Minutes, detailed action notes of the last meeting, and action log:

The minutes and detailed action notes were accepted as an accurate record of the meeting subject to correction of minor typographical errors. Members were provided with an update on progress against actions due for this month, these were noted, and items closed were agreed.

4. Formulary recommendations:

- **New: Recommendation 152 - Daily tadalafil for the treatment of erectile dysfunction**

This formulary recommendation has been drafted following the approval of daily tadalafil 5mg tablets in this setting as Amber 1 in line with criteria discussed at the October IMOC meeting. The recommendation links to the Acute Provider Collaborative (APC) adult urology guideline, which is pending an update to reflect this approval. No comments were received through the virtual Triage Panel review. There were no comments from members and the recommendation was approved by consensus.

- **Withdrawal notification: Recommendation 043 - Daily tadalafil for the treatment of erectile dysfunction**

This grey "red, amber, green, grey" (RAGG) categorised recommendation is being withdrawn and replaced by recommendation 152 following the approval of daily tadalafil 5mg tablets as outlined previously. There were no comments from members and the withdrawal notice was approved by consensus.

5. Formulary submission: Nephrotrans™ (sodium hydrogen carbonate) for the treatment and prophylaxis of metabolic acidosis in adults with chronic renal impairment

This formulary submission originates from a consultant nephrologist. The application requests formulary inclusion of Nephrotrans™(sodium hydrogen carbonate) for the treatment of metabolic acidosis and for maintenance treatment against recurrence of metabolic acidosis in adults with chronic renal impairment. The application requests an Amber 1 category in this setting. Nephrotrans™ is a gastro-resistant soft capsule formulation of sodium bicarbonate and the application requests its use as a second line option in patients who are unable to tolerate the GI side effects of standard release sodium bicarbonate capsules. It is anticipated that better tolerance of Nephrotrans™ will reduce non-adherence associated with standard sodium bicarbonate capsules and prevent complications resulting from unmanaged metabolic acidosis, such as hyperkalaemia.

- **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 Nephrotrans™ in this setting. The information presented also included the estimated resource impact for use of Nephrotrans™. The resource impact of the submission is within the financial threshold that the Committee has delegated authority to approve.

Renal disease is the most common cause of metabolic acidosis, which is a disorder related to the decrease of blood pH due to inadequate pH buffering in the blood. In patients with chronic kidney disease (CKD), non-pharmacological management involves dietary adjustments alongside bicarbonate or citrate supplementation. Oral sodium bicarbonate is listed in the SEL adult formulary as a standard capsule, however, is not RAGG categorised. The summary of product characteristics (SPC) for sodium bicarbonate recommends a mean dosage of 3 to 5 grams per day. The SPC lists stomach pain and flatulence as undesirable effects of unknown frequency with other sources reporting side effects such as belching and bloating. This application identifies a cohort of patients who are unable to tolerate the standard formulation due to GI side effects and may benefit from Nephrotrans™ gastro-resistant formulation.

With respect to the evidence base, there is limited evidence available on gastro-resistant (GR) formulations of sodium bicarbonate and no evidence was identified to support its use in the proposed population. Robust evidence to suggest that Nephrotrans™ has fewer GI side effects compared to standard sodium bicarbonate and to support its use as a more tolerable second line option is lacking as no head to head data currently exist. One phase 3 randomised control trial compared the efficacy of Nephrotrans™ versus placebo in correcting bicarbonate levels in renal transplant patients with a primary outcome of improving renal function (estimated glomerular filtration rate [eGFR]) . The results over the study period showed that Nephrotrans™ resulted in effective correction of metabolic acidosis but reduction in eGFR decline were not demonstrated. GI side effects were reviewed as a secondary outcome, with both groups reporting similar levels of incidence of infections, GI disturbances and cardiac disorders. With respect to safety, whilst the available evidence does not suggest that Nephrotrans™ has a better side effect profile when compared to standard sodium bicarbonate, no new safety concerns were identified. The incidence rates of adverse drug reactions (ADRs) are not well described in the literature and SPCs for both formulations as incidence frequencies are recorded as unknown. Data suggest that GI side effects are very common in sodium bicarbonate replacement, however the rates at which these limit treatment are not captured.

- **Applicant's presentation**

The applicant was in attendance to present the submission and answer questions. The applicant's declaration of interest was noted. The applicant confirmed that the intended use of Nephrotrans™ is for the correction of metabolic acidosis mainly in renal patients and treatment of hyperkalaemia. This will help prevent the long term negative effects of acidosis in the bones and kidneys.

In response to a query requesting further information on the applicant's previous experience with Nephrotrans™ outlined in the application, the applicant outlined that Nephrotrans™ has been used for at least three years in a small cohort of about 20-30 patients. These patients typically have advanced kidney disease or co-morbidities including diabetes or were post-simultaneous pancreas and kidney transplantation. The patients often received sodium bicarbonate doses up to 4.5 grams per day and experienced symptoms such as bloating, nausea and vomiting with standard preparations of sodium bicarbonate which often led to poor compliance and treatment failure or discontinuation. A significant proportion of this patient group have tolerated Nephrotrans™ better than standard sodium bicarbonate, including patients who previously refused to continue standard sodium bicarbonate treatment. There were very few patients who did not experience a benefit with Nephrotrans™ and the applicant confirmed that in these patients it would be appropriate to switch back to standard preparations of sodium bicarbonate. The applicant agreed to extend the trial period of standard sodium bicarbonate from two to four weeks to allow sufficient time to assess patient tolerability. The Committee were advised that intolerability is determined by patient reporting; when patients refuse to continue treatment or take the prescribed dose due to intolerable GI side effects, they are suitable for Nephrotrans™ treatment. It was clarified that there isn't a low threshold for intolerability, but the severity of acidosis, hyperkalaemia and the patient's wellbeing are all considered - sometimes the dose is split during the day and then reassessed as patients often have better tolerability to sodium bicarbonate at lower doses. The applicant advised that the severity of acidosis and hyperkalaemia would determine when to initiate Nephrotrans™. If the acidosis was deemed severe, the specialist would initiate prescribing; if the acidosis was less severe, the GP could commence prescribing.

The applicant clarified that few patients are admitted for IV sodium bicarbonate, which is the only alternative treatment for very severe cases currently. In the majority of cases, patients will stop treatment or reduce their dose of standard sodium bicarbonate and but this may lead to further health complications. In response to a query regarding the difference in the application cohort and the evidence review population, it was clarified that ‘post-transplant’ in the application referred to patients who no longer required bicarbonate due to a good working renal graft/renal function who were no longer classified as having CKD. The studies likely refer to patients who have failed transplants. Nephrotrans™ will be used in a small number of patients with advanced CKD stage 4 or 5 pre-dialysis or patients with failing transplants. The applicant advised that if Nephrotrans™ was not available on the formulary, theoretically there would be an impact on hospital admissions due to acidosis and increased urgent care attendance due to hyperkalaemia, especially in people with diabetes. The Committee were advised that both standard sodium bicarbonate and Nephrotrans™ shared the prescribing descriptor ‘bicarbonate 500mg capsules’ and brand prescribing may be required to prevent mis-selection in primary care.

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

Members discussed the application and agreed that as Nephrotrans™ is the gastro-resistant equivalent of standard sodium bicarbonate with better tolerability based on the applicant’s experience, it would be suitable for inclusion onto the formulary as a second line option for patients who find the GI effects of standard sodium bicarbonate intolerable (as described in the application). Whilst the evidence base is limited, members agreed that the availability of Nephrotrans™ offers an alternative that could prevent patient deterioration and resultant hospital admissions. Members considered the RAGG category and agreed that Nephrotrans™ as Amber 1 would be acceptable. Members highlighted that the cost of Nephrotrans™ is three times that of standard release preparations and it was agreed that if patients experienced no benefit with Nephrotrans™, they would be switched back to standard sodium bicarbonate preparations, at potentially a lower dose. This information will be included within the formulary recommendation.

Committee members agreed by consensus to approve the inclusion of Nephrotrans™ onto the formulary as Amber 1 as a second line option in patients who had trialled standard sodium bicarbonate capsules for at least four weeks and had intolerable GI side-effects. Patients will be switched back to standard release preparations if the use of Nephrotrans™ showed no benefit.

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

6. Formulary submission: Cytisine for the treatment of tobacco dependency in adults

This formulary submission originates from a Consultant Respiratory Physician and requests the use of cytisine as a first line treatment option to reduce nicotine withdrawal and cravings to improve the chances of a successful smoking quit attempt. The application requests a Green RAGG category and if approved, the intention would be to update the draft SEL chronic obstructive pulmonary disease (COPD) guideline to include cytisine. Members were advised that existing smoking cessation public health guidance from the National Institute for Health and Care Excellence (NICE) is being updated to incorporate cytisine in smoking cessation, due for publication in early 2025. Any approval provided by the committee for this submission will therefore be subject to review and alignment with NICE guidance once published. In line with the IMOC Terms of Reference, the Committee would not routinely consider applications for presentation when NICE guidance is due for release within 12 months. However, members agreed to proceed with this application as it has been in progress for a significant time prior to NICE announcing a rapid review of their guidance.

- **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 cytisine in this setting. The information presented also included the estimated resource impact for use of cytisine. The resource impact of the submission is within the financial threshold that the committee has delegated authority to approve.

Tobacco smoking is one of the most significant health problems worldwide. It causes several non-communicable diseases and morbidity, including COPD, emphysema, cardiovascular disease, and cancer. In 2023, prevalence in England was 13.6% with almost 80,000 deaths caused by smoking. Data in SEL also demonstrates that smoking is attributable to over 9,000 hospital admissions and over 4,000 premature deaths each year. Cytisinicline, known as cytisine, is a nicotinic acetylcholine agonist with a weaker effect than nicotine, but with a higher affinity for the receptor, and therefore well suited to be used as a weaning treatment in smoking cessation therapy. There is a complex dosing regimen, and patients should stop smoking no later than day 5 of treatment. As noted earlier, NICE is currently updating public health smoking cessation guidance to include cytisine. The current draft updated NICE guidance states that cytisine has a higher success rate, placing it alongside varenicline, combination nicotine replacement therapy (NRT) and nicotine electronic cigarettes (e-cigarettes).

With respect to the evidence base, two recent Cochrane meta-analysis from 2023 provide the most up to date, high quality evidence for pharmacotherapies for smoking cessation. One pairwise meta-analysis in over 40,000 patients found that cytisine demonstrated statistically significant superiority over placebo for abstinence after >6 months (205 vs. 158 abstainers per 1000 people). Cytisine was also superior to NRT for abstinence rates (218 vs. 153 abstainers per 1000 people). Varenicline had the highest smoking cessation rates vs placebo, but this was not statistically significant. Rates of adverse effects were similar between cytisine vs. placebo/no treatment. Similar rates of serious adverse effects were observed with cytisine vs NRT, but lower for cytisine vs. varenicline. The other meta-analysis found that cytisine, nicotine e-cigarettes and varenicline to be the most effective treatments. Serious adverse effects were not significantly different between these interventions vs. no intervention. Cytisine demonstrated superiority to NRT, bupropion, nortriptyline and placebo e-cigarettes. There was broadly comparable efficacy between cytisine and varenicline, nicotine e-cigarettes and combination NRT noting there is significantly more data for varenicline.

With respect to safety, evidence indicates that cytisine is well tolerated. The main adverse effects reported are gastrointestinal symptoms (e.g. nausea and constipation). The SPC also lists fatigue, sleep disorders, weight gain, tachycardia and rash among several very common side effects. Overall, cytisine appears to have a more favourable side effect profile than varenicline. The formulary application does not state whether cytisine is intended as an alternative option to established treatments such as varenicline and NRT, or whether it is intended to be more routinely used at the same point in therapy as these treatments.

- **Applicant's presentation**

The applicant was in attendance to present the submission and answer questions. The applicant's declaration of interest was noted. The meeting Chair explained to the applicant that in view of updated NICE public health guidance due for cytisine in early 2025, any recommendation made by the committee would be subject to review following publication of the updated NICE guidance. The applicant stated that they co-chair the SEL Tobacco Dependence Oversight Group, which focuses on tobacco harm reduction across the Integrated Care System (ICS). The Tobacco Dependence Group has endorsed the use of cytisine for smoking cessation. Cytisine was considered due to the ongoing supply disruption of varenicline and a need to improve poor outcomes in the context of reduced number of treatments for smoking cessation. It was noted by committee members that the supply issue with varenicline has now resolved. Evidence suggests that cytisine has a positive profile for safety, effectiveness and cost-effectiveness.

In response to a query regarding the patient management of the complex dosing schedule for cytisine and how patients would be counselled to ensure compliance, the applicant advised that pharmacotherapies are most effective in combination with behavioural support. Patients will be supported with compliance by a tobacco dependence advisor in hospital, and through the borough-led quit smoking programmes in the community. It relation to smoking cessation therapy in the emergency department, the applicant confirmed that acute nicotine withdrawal treatment is best achieved with dual NRT, followed by a collaborative discussion with a tobacco dependence specialist. Cytisine should be available for patients as a treatment option. This would not be considered an additional cost because most patients require more than one treatment to help them quit. Ideally, patients should be prescribed a whole treatment course at discharge, however it is important for primary care to be educated and empowered to prescribe smoking cessation therapies to improve patient access and there is ongoing work to address this.

The applicant informed the committee that the usual course length is 25 days, but patients could take cytisine for up to 12 weeks if effective. If the treatment fails, it could be used again after assessment of why it may not have worked and following a holistic patient review after a break of 2-3 months. Committee members confirmed the licence for cytisine only covers a 25 day treatment course at a time and only the licensed regimen has been requested in the formulary application. The applicant confirmed that cytisine would be a first line option alongside other existing options giving patients a choice based on suitability. In response to a query regarding stimulant properties of cytisine, the applicant advised that there is no evidence to suggest that cytisine has stimulant properties that could make it prone to misuse. Members were also advised that varenicline is back in stock according to the Specialist Pharmacy Services supply tool.

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

A comment was raised that the existing formulary included smoking cessation options of NRT, varenicline and bupropion do not have RAGG categories assigned as this aligns to borough specific methods of supply. For example, some boroughs have designated smoking cessation services commissioned by the local authority, so GPs do not prescribe. It was queried whether cytisine should be noted on the formulary in a similar way for borough specific prescribing arrangements. Members were advised that in line with local prevention strategies, a Green category would support and enable access to smoking cessation services in different healthcare settings to make every contact count. There is also a big push as part of Vital 5 and the local system sustainability programme to promote smoking cessation so improving access to stop smoking medicines would support this. A note can be included on the formulary entry to check local arrangements. Members discussed the licensing for use of cytisine and agreed that only the licensed use for 25 days would be approved. If there is an appetite to use the off-label 12 week course, the usual governance would apply and an application would need to be made to the committee.

Members agreed by consensus to approve cytisine with a RAGG category of Green but with a criterion to involve local smoking cessation services. Additionally, it was agreed by consensus to categorise varenicline and NRT as Green with the same caveats as cytisine on the formulary.

Members were also requested to comment on the format of the evidence review presentation, which had been delivered differently to test the use of a slide deck. Members were supportive and included a suggestion to keep the overarching evidence review document but supplement it with a fewer number of slides containing the key points.

ACTION: Formulary recommendation to be drafted and presented at a future meeting
ACTION: Formulary to be updated as per discussions once the formulary recommendation is published

7. Formulary requests to include licensed formulations to replace unlicensed specials:

(i) Sertraline 50mg in 5ml oral suspension (Colonis Pharma) in adults and paediatrics
(ii) Azathioprine (Jayempi™) 10mg in 1ml oral suspension in paediatrics

The lead pharmacists were in attendance to present this item. Currently, patients who cannot take the tablet formulation of sertraline or azathioprine are prescribed unlicensed liquid specials as there were no licensed liquids available. Recently, licensed liquids for both sertraline and azathioprine have become available. The application is requesting both licensed liquids to be included on the formulary as an unlicensed to licensed product switch.

(i) Sertraline 50mg in 5ml oral suspension (Colonis Pharma) in adults and paediatrics

In the last year, two licensed oral suspensions of sertraline have been manufactured. As the 100mg/5ml preparation contains significant concentrations of alcohol, it would not be suitable for the paediatric cohort and is not for consideration. The request is to add the 50mg in 5ml oral suspension of sertraline manufactured by Colonis Pharma to the adult and paediatric formularies. A full excipient evaluation has been carried out and it has been deemed suitable for the paediatric cohort. Prescribing costs of sertraline liquid specials have increased since October 2023 and introduction of the licensed sertraline liquid to the formulary would provide better stability in price compared to the unlicensed liquid specials. The licensed liquid is £200 per 150ml bottle, and in line with common practice, it is recommended that sertraline liquid is reserved for patients who unable to take the tablet formulation. This formulation has a two month expiry date which is advantageous for patients and does not require storage in the fridge. The introduction of the licensed liquid is expected to support the current specials spend and the anticipated cost impact is within the financial threshold delegated to the committee.

(ii) Azathioprine (Jayempi™) 10mg in 1ml oral suspension in paediatrics

A licensed liquid of azathioprine (10mg/ml) has become available. The licensed liquid has a greater cost impact than the unlicensed special (£1.25/ml v £0.52/ml), however it does have a longer 12 week expiry from opening. There is very little primary care prescribing as most prescribing occurs within paediatric specialist settings; whilst prescribing costs are anticipated to increase with use of the licensed product, the cost impact remains within the financial threshold delegated to the committee. The specialist teams have been reminded to regularly review the rationale for azathioprine liquid prescribing and switch to tablet formulations wherever possible. The paediatric immunomodulatory shared care agreement would require updating to reflect inclusion of the licensed azathioprine liquid if approved.

Members agreed by consensus to include licensed liquid formulation of sertraline to the adult and paediatric formulary and the licensed azathioprine liquid formulation to the paediatric formulary.

ACTION: Paediatric immunomodulatory shared share agreement to be updated to incorporate the licensed liquid formulation for azathioprine
ACTION: Appropriate formulary (paediatric/adult) to be updated with sertraline and azathioprine licensed liquids

8. Resource to support safer prescribing of continuous glucose monitoring (CGM) devices in primary care

The authors were in attendance (on behalf of the diabetes sub-group) to present this item. The presenters declaration of interest was noted. The presenters noted that a need for this resource was identified through the diabetes sub-group. Over the past few years, the number of CGM devices available has increased with some having very similar sounding names and packaging and there is a risk that this may lead to errors in prescribing, selection and dispensing. The devices have many significant differences including functionality, application and connectivity and therefore it is essential that the right device is issued to ensure the individual can safely manage their glucose levels. The resource aims to support safety by providing information to help reduce the risks of selection errors with CGM devices. The document includes tailored information for prescribers and dispensers, and images of the relevant CGM devices are included as a visual reference.

Members welcomed the guidance and recommended that the statement at the top – "To: South East London Primary and Secondary Care Colleagues" will be removed as the resource is not intended to be sent as a letter. The presenters also advised that a couple of minor formatting amendments have been noted since the meeting paperwork was circulated, which they will also make.
Committee members agreed by consensus to approve the CGM resource.

ACTION: Authors to amend document and return to IMOC team to submit for IMOC Chair's ratification.

9. Additional supporting data for the use of apixaban for thromboprophylaxis following deep venous stent insertion post thrombolysis for deep vein thrombosis

This item relates to a formulary application from Guy's and St. Thomas' NHS Foundation Trust (GSTT) originally presented to the committee in February 2023. The notes extract from the February 2023 meeting and evidence review was included to remind members of the previous discussions. The application requested the use of apixaban to reduce and prevent extension of clot burden around deep venous stent inserted post-catheter directed thrombolysis as part of first line treatment for acute subclavian and iliofemoral deep vein thrombosis (DVT). At the time, members acknowledged there was insufficient published evidence to support the use of apixaban as first line treatment in this setting. As approval by consensus could not be reached, the decision was deferred until the applicant could present additional supporting data for the use of apixaban collated by the GSTT vascular team.

The original formulary applicant (a Consultant Vascular Surgeon) was in attendance to present the data along with a Consultant Haematologist and specialist Cardiovascular Pharmacist. Committee members were reminded that GSTT is a national tertiary centre for the management of deep venous disease. The presenters shared a slide deck (not previously circulated to the committee) summarising the data they had collated and shared in a document within the agenda paperwork. It was noted that post thrombotic syndrome (PTS) is a complication of deep vein thrombosis (DVT) that occurs in approximately one third of patients causing long-term morbidity including pain, leg swelling, skin damage and ulceration. Treatment of PTS includes anticoagulation to reduce further DVT, compression such as compression hosiery or dressings and for more severe disease, venoplasty and venous stenting. It has been recognised that anticoagulation is needed following venous stenting to maintain patency of the stent and prevent further symptoms following the procedure, and additionally to reduce the risk of further thrombosis in patients at a high-risk of recurrence given their underlying thrombotic tendency. DOACs are recommended first line by NICE for venous thromboembolism, although the indication being considered by the committee is off-label use. The preference for apixaban over other DOACs in this setting is based on lower bleeding rates compared to warfarin or low molecular weight heparin (LMWH). Additionally, food does not have a significant impact on apixaban bioavailability and theoretical evidence suggests the pharmacokinetic parameters of apixaban results in more stable anticoagulation. These attributes together with the ease of administration are likely to promote good compliance and better long term patient outcomes.

Committee members were informed that following stent insertion a LMWH would be supplied to patients for the first 6 weeks following treatment and then patients would be switched to apixaban (following a satisfactory Duplex scan) to continue for at least one year at a dose of 5mg twice daily with a request for primary care to take over this prescribing after 3 months. Apixaban use was initiated by the service in response to the COVID-19 pandemic to reduce the need for frequent patient monitoring and support the clinical burden.

A retrospective review was performed of GSTT electronic records for patients who had undergone a venous stenting procedure between January 2014 to March 2023. Patients were classified by the period of initial venous intervention, either with warfarin for first-line oral anticoagulant up to February 2020 or apixaban for first-time oral anticoagulant after March 2020.The primary outcome was primary patency of venous stenting over 6-months and the secondary outcomes were long-term patency, reintervention rates, development of other VTE events and bleeding. A total of 565 patients were reviewed with 457 warfarin patients and 108 apixaban patients. The age at intervention was similar for both warfarin and apixaban. The duration of follow up was longer for warfarin as patients started treatment earlier and the majority of treatment indications were for PTS. It was noted that a significantly higher number of apixaban patients received concomitant antiplatelet therapy, however this had a minimal impact on the bleeding rates. The results show that primary stent patency during the first 6-months following venous stenting appears similar between warfarin and apixaban at approximately 60%. The long-term primary and overall patency data was also similar although the rates of reinterventions were higher in the warfarin group, likely due to the longer period of follow up as well as improvements in procedures, stents and other factors over time. With respect to safety, the bleeding rates were in keeping with general expectations for VTE patients and similar efficacy for VTE prevention was observed in both groups. There were 3 episodes of major haemorrhage reported, however none of these involved apixaban as a contributing factor and no major haemorrhages have been detected since switching to apixaban as the first-line oral anticoagulant.

In response to a query from the committee, the presenters confirmed the specialist team would supply the first 3 months of treatment and primary care would be asked to provide continuous prescriptions after this. Committee members were advised that patients requiring venoplasty after initial stenting often benefit from a short course of clopidogrel (6 weeks - 3 month) which is prescribed solely by the specialist team and is not for primary care prescribing. This decision is discussed in a multidisciplinary meeting involving haematology. In response to a query regarding the comparable efficacy of apixaban vs. warfarin in this setting, the committee were advised that apixaban has been very well tolerated and there does not seem to be an increase in re-intervention rates, furthermore compliance is better with apixaban than warfarin. For patients with antiphospholipid syndrome or significant renal impairment, warfarin is still first line. The presenters advised that the majority of patients (~ 80%) will need treatment beyond one year, especially patients who have a history of unprovoked venous thrombolytic events and patients have regular follow up from specialists during the first year post-stenting. The applicants confirmed that the updated internal Trust guideline will go through the GSTT Drugs and Therapeutics Committee for governance and sign off once an IMOC decision is available.

Members thanked the presenters for a comprehensive presentation of the follow up data. The presenters confirmed that they plan to formally write up their study for publication. Members discussed the additional data that was presented and were satisfied that the efficacy and safety of apixaban were evident in this setting. As per the data presented at the February 2023 IMOC meeting, the resource impact of the submission is within the financial threshold delegated to the committee.

Members agreed by consensus to approve apixaban in this setting with an Amber 2 category. The first 3 months of treatment will be provided by the specialist team after which the GP can be requested to take over under an individual patient management plan. Patients requiring treatment beyond 12 months would be reviewed by the specialist multidisciplinary team at 12 months, then annually thereafter.

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

10. NICE Technology Appraisal discussion - Red, Amber, Green, Grey (RAGG) categorisation

NICE have recently published several technology appraisals (TAs) and the committee was requested to discuss these in order to agree a RAGG category and acknowledge their cost impact:

(i) Vibegron for treating symptoms of overactive bladder syndrome (OAB) - NICE TA 999

NICE has recommended vibegron (Obgemsa™) as a treatment option in this setting, at the same point in therapy as mirabegron, which is RAGG categorised as Green. The committee was asked to consider whether it would be suitable for vibegron to also be classified as Green and included on the formulary as an equal therapy to mirabegron. The estimated cost impact of vibegron, up to year 5 of implementation (steady state) based on the NICE costing template, is within the financial threshold delegated to the committee. It was noted that in the next few years mirabegron is likely to come off patent, which may make it more cost-effective, however the NICE costing model does not account for this. The APC urology guideline (OAB treatment pathway) will require an update to reflect the availability of this TA.

(ii) Relugolix for treating hormone-sensitive prostate cancer – NICE TA 995

NICE has recommended relugolix (Orgovyx™) as a treatment option in this setting and an Amber 1 RAGG category was proposed, in line with the use of gonadorelin analogues in this setting. The existing treatments are injectables and relugolix is an oral formulation. The estimated cost impact of relugolix up to year 5 of implementation (steady state), based on the NICE costing template, is within the Committee's delegated financial threshold. There is also a potential for resource saving as the alternative treatments are injectables and the introduction of relugolix as an oral formulation is expected to release staff and service capacity.

(iii) Latanoprost-netarsudil (Roclanda™) for previously treated primary open-angle glaucoma or ocular hypertension - NICE TA 1009

NICE has recommended latanoprost-netarsudil eye drops as a treatment option in this setting. The existing glaucoma pathway is under review to incorporate latanoprost-netarsudil. The majority of existing glaucoma treatments are Amber 2 on the formulary with a few being classified as Red. Feedback from Trust colleagues suggests it would be suitable for latanoprost-netarsudil to be categorised as Amber 2. The estimated cost impact of latanoprost-netarsudil up to year 5 of implementation (steady state), based on the NICE costing template, is within the committee's delegated financial threshold .

Members agreed by consensus that vibegron can be classified as Green, relugolix as Amber 1 and latanoprost-netarsudil as Amber 2.

ACTION: Adult formulary to be updated to include vibegron, relugolix (prostate cancer) and latanoprost-netarsudil in line with discussions

- **Standing items/Items for information only**

Formulary submissions tracker
Noted.

- NICE Technology Appraisal (TA) Guidance Summary - ICS & NHS England attributed medicines: The summary was noted, and RAGG categories were agreed by consensus, where it was possible to confirm the RAGG status.
- *For information and noting:*

- Adult and paediatric formulary update – noted by Committee members.
- World Antimicrobial Awareness week activities – noted by Committee members.
- Formulary amendment to include off-label use of morphine sulphate orodispersible tablets (Actimorph®) for breathlessness in palliative care. The original Actimorph® request was approved at the March 2023 IMOC meeting as a substitute for morphine liquid/tablets. This request included palliative care use, however this had not been reflected in the formulary and has now been corrected. Morphine sulphate currently has no RAGG category assigned for breathlessness in palliative care, members agreed to discuss this at a future meeting alongside upcoming requests for oxycodone and lorazepam use in breathlessness associated with palliative care.

ACTION: RAGG categorisation for the use of Actimorph® in palliative care to be agreed at a future IMOC meeting

11. Any other business
The December meeting will be a hybrid meeting.

IMOC dates for next 3 months

Date	Time	Venue
Thursday 19th December	2pm – 4:30pm	Hybrid meeting
Thursday 16th January 2025	2pm – 4:30pm	MS Teams
Thursday 20th February 2025	2pm – 4:30pm	MS Teams