South East London Integrated Medicines Optimisation Committee Meeting
20 October 2022 (Meeting held via MS Teams)
Final Minutes

1. Welcome, introductions and apologies

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

2. Conflict of interests – declarations and DOI refresh

The Chair asked that any conflicts of interest with the meeting agenda be declared and that any outstanding declarations be returned. No conflicts were raised.

3. Minutes of the last meeting and action log

The action notes and minutes were accepted and approved as an accurate record pending amendments to content under the Bijuve™ discussion and minor grammatical errors.

Members were provided with an update on progress against actions due for this month, these were noted, and items closed were agreed.

4. Steroid emergency card guidance and patient information leaflet (PIL) for primary care

The author was in attendance to present this item, which aims to support implementation of the National Patient Safety Agency alert on steroid emergency cards (issued in 2020). The guidance document advises how to identify patients with adrenal insufficiency, who should issue the cards, the differences between the blue steroid card & the steroid emergency card, where to obtain cards and information on the Arden's tool to support with the NPSA actions. The patient information leaflet is intended for use in primary care and once approved, will be made available on the patient-facing section of the SEL ICB website. It is based on the PIL in use at King's College Hospital (KCH) and has been adapted for use in primary care.

Both documents have undergone consultation. Members provided feedback on the documents and requested amendments including adding an introduction to the guidance to provide context. Clarification was also requested regarding whether the sick day rule guidance in the PIL is for patients on regular steroids, whose responsibility it is to provide the leaflet to the patient and whether a blue steroid card should be provided alongside the emergency steroid card. Members also suggested that the PIL is streamlined and consideration given to excess information being removed, such as the healthcare professional dosing information. Minor formatting comments were also made, such as adding references to the guidance and reviewing some of the language used in the PIL. The Committee also recommended that the documents are shared with the IMOC's respiratory sub-group to ensure they are satisfied with the advice provided on inhaled corticosteroids.

Action: Author to update the guidance and leaflet in line with comments and share with the respiratory sub-group for review. To be re-presented at IMOC once the amendments have been progressed.

5. Formulary recommendations

- **New**: Pitolisant (Wakix™) for the treatment of cataplexy within type 1 narcolepsy (narcolepsy with cataplexy)

The Committee were asked to note that the pathway had been included for approval following the last IMOC meeting rather than for information (as noted on the agenda). Minor comments from the Triage Panel review of the formulary recommendation have been incorporated. Minor corrections will be made to the pathway and a link to the formulary recommendation added to the pathway and vice-versa. Members provided some minor formatting comments on the pathway to make clearer the actions in the footnotes relating to the slow withdrawal of antidepressants. A suggestion was also made to linking to guidance provided by SLAM on withdrawing antidepressants, if this is available, or to add contact details for the service.

The recommendation and pathway were approved by consensus pending these amendments.

ACTION: Authors to amend pathway and formulary recommendation, once amended to be progressed for IMOC chair's ratification.

- **New**: Insulin degludec 100 units/ml and 200 units per ml (Tresiba® FlexTouch and penfill cartridges) for the treatment of diabetes mellitus in adolescents and children aged 12 years and above. It was clarified that use in children with Type 2 diabetes was in line with the existing formulary recommendation and wording will be added to the category section to clarify this.
- **New**: Bijuve™ (oestradiol 1mg micronised progesterone 100mg) for continuous combined hormone replacement therapy for oestrogen deficiency symptoms in postmenopausal women. The formulary recommendation will be updated in line with earlier discussions in the meeting to reflect that prescribing the components separately is more expensive vs. Bijuve™.

The insulin degludec and Bijuve™ formulary recommendations were approved by consensus pending the amendments requested.

ACTION: Recommendations to be updated and progressed for IMOC Chair's ratification.

6. Updated SEL IMOC Terms of Reference

An Integrated Care Board (ICB) version of the SEL IMOC terms of reference (ToR) were approved by the ICB on 1 July 2022. The expiry date of the existing Committee ToR (pre-ICB) is the end of October – this has enabled the Committee to run for a brief time and amendments to the Board version of the ToR to be determined. A detailed summary of the changes was provided in the agenda pack and the Committee taken through these. The ICB's Assurance Team have also confirmed that it is acceptable to have a version of the IMOC ToR for publication on the IMOC website for use with stakeholders with the established Committee branding. There will be a version in the ICB handbook that is formatted slightly differently, for example the approval cover sheet won't be included, however the content will be the same. Some content in the ToR had previously been amended by the Assurance Team to make all Committee ToRs similar. However, in this review, amendments have been made to certain sections of the ToR to align the wording back to the established IMOC processes. These amendments have been made following discussion with and approval from the Assurance Lead and are detailed in the agenda pack.

No comments were raised by Committee members and the updated ToR were approved by consensus.

ACTION: ToR to be progressed for ratification by the Quality and Performance Committee.

Post meeting note: *An additional amendment was made to section 7 of the ToR following some separate feedback after the IMOC meeting in relation to chairing arrangements. The section has been re-worded following consultation with the Assurance Lead and signed off via IMOC Chair's action.*

7. SEL IMOC workplan Q2 2022/23 update

The SEL IMOC workplan was presented noting some slippage on timescales. In particular the action to develop a SEL-wide wound care formulary, it was noted that meetings with community providers had been set up to discuss an approach. Members agreed to the work plan being updated with the new timescales for the website.

The Committee noted the workplan update.

8. Formulary submission for budesonide (Jorveza™) 1mg orodispersible tablets for the maintenance treatment of eosinophilic oesophagitis

This formulary submission originates from gastroenterology at GSTT and is supported by KCH and LGT. The application requests the use of budesonide 1mg orodispersible tablets (Jorveza™) for the maintenance treatment of eosinophilic oesophagitis (EoE) following a 6 - 12 week induction course.

- **Application and evidence review**

The Formulary Pharmacist presented an overview of the efficacy evidence for the use of Jorveza™ in this setting, the detailed review was provided within the meeting agenda pack. The information presented also included the estimated resource impact for Bijuve™, the resource impact of the submission is within the financial threshold that the Committee is authorised to approve. The Committee were advised that budesonide (Jorveza™) orodispersible tablets are recommended as an option by NICE for inducing remission of EOE in adults and are on formulary for inducing remission. A recent licence extension for Jorveza™ has made available the maintenance option, however this has not yet been reviewed by NICE. This is a long-term condition and treatment options are as per the British Society of Gastroenterology guidelines - diet restriction, proton pump inhibitors (PPIs) and Jorveza™. Other options include the off-label use of fluticasone inhaler.

- **Applicant's presentation**

The applicant was in attendance to present the submission and field any questions. The applicant's DoI was noted. The applicant introduced the application, noting that this currently is the best treatment option for these patients with this allergic condition of the oesophagus, which severely impacts quality of life. The approach taken by the specialist teams is to induce remission on 1mg twice daily and then maintain the patient on 0.5mg twice daily.

The applicant responded to queries from members. This included clarifying that the safety profile is favourable and as a low dose (0.5mg twice a day) is employed, cortisol suppression and effects on bones are minimised, thus monitoring outside symptomatic monitoring (e.g. for bone density and glucose) would not be required. About 10% of cases developed oral candidiasis as a side effect, which is usually treated with nystatin, or by teaching the patient different techniques for swallowing the medicine. A 12 week induction course will be used in all patients and relapses would move to maintenance treatment. Criteria for stopping treatment include patient preference and development of significant candidiasis. Drug holidays are not employed - the applicant advised that data are available for use up to 3 years however the literature does not include data on drug holidays.

In terms of the treatment pathway, the applicant confirmed there is no standard approach for all patients and that this involves a patient centred approach. Proton pump inhibitors (PPIs) are not first line in all patients, this would be dependent upon the presenting clinical symptoms (for example, in EOE patients with reflux or severe hernia, a PPI is preferred). Additionally, the dietary change approach requires a series of follow ups and six endoscopies to assess the response of the re-introduction of 6 ingredients into the diet.

The applicant clarified that patients are not discharged from the service and are routinely monitored by the gastroenterology team. There are likely to be off-set costs from a reduction in the number of multiple endoscopies required for dietary elimination or to check for recurrence and a reduction in the need for dilatation procedures

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

The Committee discussed the application and acknowledged that the arguments for supporting the use of Jorveza™ were convincing clinically. Members discussed the cost implications of the treatment, which whilst within the thresholds that the Committee can approve, may contribute to an already challenging financial climate. Members agreed that some of this additional cost could be mitigated through a pathway approach whereby consideration is also given to other treatment options alongside Jorveza™. Whilst NICE guidance does not stipulate that a PPI must be trialled before Jorveza™, committee members felt that where it was clinically appropriate, the use of PPIs should be promoted and this should be reflected in the formulary recommendation along with the other treatment options. It was noted there may also be benefit and savings from a reduction in the need for repeated endoscopies and dilatation procedures. Additionally, from a patient safety perspective, repeated endoscopies could increase the risk of perforation of the gullet.

Members agreed by consensus that:

- Given the universal prescription of the 1mg to induce remission, the full 12 week induction course should be prescribed and supplied by secondary care, to ensure an appropriate risk share, with primary care prescribing the maintenance dose where there is a clinical decision for the patient to continue treatment.
- A GP information sheet should be developed
- The RAGG (red, amber, green, grey) category for Jorveza™ in this setting was agreed in principle by consensus as Amber 2. This is pending the GP information sheet.
- The formulary recommendation will be time limited to12 months with a requirement for the applicant to coordinate a report back to the Committee on patient numbers and outcomes.
- The formulary recommendation will be issued once the GP information sheet has been drafted and approved by the Committee.

ACTION: Applicant to develop information sheet for primary care
ACTION: Formulary recommendation to be drafted after information sheet has been developed

9. Formulary inclusion of estradiol patches, estradiol tablets, and progesterone tablets for pubertal induction for girls with primary or secondary ovarian insufficiency, and in those with delayed puberty

A consultant endocrinologist was in attendance to present this formulary request, which seeks to formalise historic use of estradiol patches & tablets and progesterone tablets in this setting as Amber 2 on the SEL formulary. The presenter outlined that GPs had routinely historically been asked to prescribe, with requests originating from paediatric endocrinology or from the adult transition clinic. Patients require pubertal induction for a variety of reasons including cancer survivors with primary ovarian insufficiency induced by chemotherapy or secondary ovarian insufficiency because of pituitary insufficiency caused by whole brain radiation, as well as girls with Turners syndrome, and children with constitutional delay. Hormonal treatment helps achieve development of secondary sexual characteristics, growth spurt and psychological maturation and adjustment. It was clarified that the use of these products in this way is off-label, however exogenous estrogen is a recognised strategy for pubertal induction in these cases, there is no alternative and has been common practice for some time. The British Society of Paediatric Endocrinology and Diabetes advocate transdermal estradiol, oral estradiol or oral ethinylestradiol regimens, which have been used at local paediatric centres and in transition endocrinology clinics. Patient choice is key and treatment options to provide a solution that worked for the girls and young women is important.

The patient numbers and cost of the treatments is within the threshold the IMOC is authorised to approve. The cost is expected to be in the baseline as the practice is already occurring.

Members approved by consensus the addition to formulary as Amber 2.

ACTION: SEL formulary website to be updated

10. Formulary inclusion of morphine sulphate orodispersible tablets (Actimorph™) as the sole immediate release morphine formulation for routine use at KCH

The Committee heard the request to add morphine sulphate orodispersible tablets (Actimorph™) to the formulary for use at KCH. The Trust will be switching from Oramorph® to Actimorph™ to contribute to cost savings as well as savings in nursing time and to reduce the risk of errors. Oramorph™ is legally classified as a schedule 5 controlled drug (CD). However, at KCH it is treated as a schedule 2 CD, which means it requires two nurses to sign out the drug. The process is time consuming as are the reporting processes in the event of any wastage or discrepancy. It was noted that LGT and GSTT treat Oramorph™ as per its legal CD schedule. Switching from Oramorph™ would also make savings on the ancillaries such as bungs and syringes which were required for each dose of Oramorph™. A switch to Sevredol™ had been considered but the 10mg tablets do not provide sufficient flexibility for lower doses compared to Actimorph™. Formulary inclusion was proposed should GP's wish to provide continuity of product for the approximately 10% of patients who may require further supplies following discharge from the hospital. The additional cost pressure for primary care is negligible and within the threshold the IMOC can approve.

Members discussed the request and several concerns were raised, including that the reliance on a single formulation could present a challenge if there were supply issues in the future. Members also highlighted a potential for confusion in primary care, given there are six different strengths for Actimorph™ and the change will increase the number of morphine sulphate brands being prescribed in primary care. It was also noted that a switch at a single Trust could lead to inconsistencies across the local healthcare system. The potential for increased workload in community pharmacies and general practice was also raised, given this would be a move from a Schedule 5 to a Schedule 2 CD. It was noted that discussions are occurring at GSTT about the possible use in a small number of specific circumstances, such as palliative care and paediatrics.

Members agreed a review of the request through the ICS Medicines Safety Network would be helpful. The Committee agreed by consensus to add morphine sulphate orodispersible tablets (Actimorph™) to formulary with a Red (hospital only) interim rating to avoid delay to the implementation of the KCH improvement plans. The formulary entry will include instructions that those patients prescribed Actimorph™ as inpatients who have a continuing need for morphine sulphate should be transferred at discharge to an alternative formulation (such as Oramorph™ or Sevredol™) listed for use in primary care within the formulary, with clear communication and instruction to primary care.

ACTION: Medicines Safety Network lead to be requested to consider Actimorph™ request at next Network meeting for review and comment
ACTION: Formulary request form to be updated to reflect adult cohorts expected at GSTT with patient numbers
ACTION: Separate request to be submitted for paediatrics if there is interest to use

11. Update to SEL IMOC Red, Amber, Green, Grey (RAGG) definitions

The Committee were informed that the updates to the RAGG definitions had been made to align better with shared care guidance and joint formulary recommendations. A query was raised about Amber 2 and Amber 3 as it was noted that some medicines such as newer anticoagulants and ADHD medications may fit in both categories. The default is to the categories agreed on the formulary website. A note will be added under the amber 3 definition to advise checking the SEL formulary website for the category. It was also suggested that a link to the “share or not to share care” flowchart is added to help users understand how the amber 2/3 category is determined. It was also recommended that an alternative to ‘lead commissioner’ should be suggested in the wording given this terminology is no longer preferred as part of ICS working.

ACTION: Author to amend document which will then be progressed for IMOC Chair’s action

12. Interface prescribing issues between primary and secondary care – dissemination of IMOC guidance

Due to time constraints, this item was deferred to a future meeting.

13. Standing items

- **Formulary Submissions tracker**

Noted.

- **NICE Technology Appraisal guidance summary – ICS and NHS England attributed medicines**

The summary was noted and RAGG categories were agreed by consensus.

14. Any other business

The Committee noted the KCH clinical lead representative is stepping down from the Committee and thanked them for their valued contribution and advice during their membership of the Committee.

IMOC dates for next 3 months

Date	Time	Venue
17th November 2022	2:00pm – 4:30pm	MS Teams
15th December 2022	2:00pm – 4:30pm	MS Teams
19th January 2023	2:00pm – 4:30pm	MS Teams