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

1. Welcome, introductions and apologies

The Chair welcomed attendees to the meeting followed by a round of introductions. 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 annual declarations be returned. No conflicts were raised.

3. Detailed action notes of the last meeting, minutes and action log:

The action notes and minutes were accepted and approved as an accurate record pending corrections to 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. Guidance for the safe switching of patients on anticoagulants for non-valvular atrial fibrillation (NVAF) to the direct oral anticoagulant (DOAC) edoxaban

The author presented this item which supports the national commissioning recommendation for the use of edoxaban as the DOAC of choice for the management of NVAF. The guidance aims to support:

- primary care to appropriately select patients who can be safely switched to the preferred anticoaglulant edoxaban
- the safe monitoring of patients prescribed DOACs in primary care

Various comments were shared by Committee members which included updates to the advice within the guidance regarding the management of bleeds, dosing in extremeities of weight and how to access specialist advice. Members highlighted the availablility of national resources to support switching of patients on anticoagulants to edoxaban. It was noted that PrescQiPP have developed a suite of supporting documents for switching patients on anticoagulants for AF to edoxaban, which would be useful to link to in the guidance.

The Committee agreed by consensus the final approval of the guidance is pending following updates to the guidance in line with discussions and re-presentation of the guidance at a future IMOC meeting.

ACTION: Guidance to be updated in line with discussions and presented at a future IMOC meeting for ratification

5. Formulary inclusion of methylprednisolone 100mg tablets for the management of multiple sclerosis relapses

The Formulary Pharmacist presented this item requesting the formulary inclusion of methylprednisolone 100mg tablets (off-label) at a dose of 500mg once a day for 5 days for the management of multiple scleorisi (MS) replases in line with NICE guidance. Methylprednisolone 100mg tablets is already routinely used for this cohort of patients. Adding methylprednisolone 100mg tablets to the formulary will formalise the existing prescribing practice. In line with current practice;the intention is that this will be Amber 1 – primary care will be requested to prescribe the 5 day course on the advice of a specialist.

The anticipated cost is within the thresholds the Committee can approve. Most of this cost is likely to be the baseline as prescribing is already occurring in primary care.

With respect to how quickly the treatment would need to be prescribed by the GP, the presenter clarified the GP is usually called by the specialist team and is informed all other causes of the relapse such as infection has been ruled out. The request to issue a prescription does not to be actioned immediately but as soon as it is feasible by the GP practice. An additional comment was raised

regarding the cost impact and whether this is based on one MS relapse per year. The presenter confirmed this is based on one MS relapse per year however the average number of relapses per year can be clarified with the specialist MS team.

Committee members agreed by consensus for the inclusion of methylprednisolone 100mg tablets at a dose of 500mg once a day for 5 days to the SEL JMF for the management of MS relapse.

Post meeting note: *The formulary pharmacist confirmed the MS Trust states people with relapsing remitting MS have around one relapse every two years.*

ACTION: Methylprednisolone 100mg tablets to be added to the SEL JMF at a dose of 500mg once a day for 5 days for the management of MS relapse.

6. Formulary recommendations

- **New:** Fiasp™ insulin (insulin aspart) for the management of diabetes mellitus in children and young people – this was drafted following the formulary application at the July 2022 SEL IMOC meeting.

- **Updated:** Calcipotriol/betamethasone cutaneous foam spray (Enstilar™) for the treatment of psoriasis vulgaris in adult patients - updated in line with the discussions at the July 2022 SEL IMOC meeting regarding the primary care dermatology guidelines.

Both recommendations have been reviewed through the Triage Panel. Committee members approved the formulary recommendations by consensus with no further comments.

7. Formulary submission: Dienogest (Zalkya™) 2mg film-coated tablets for the treatment of endometriosis:

This formulary submission originates from GSTT – the applicants are a gynaecology and endometriosis clinical nurse specialist and an obstetrics and gynaecology registrar. The application requests the use of dienogest (Zalkya™) 2mg film-coated tablets for the treatment of endometriosis related pain where analgesia has been ineffective, or as an alternative to a GnRH agonist before or after surgery, or in patients who are not suitable for surgery.

- **Evidence review**

The Formulary Pharmacist presented an overview of the efficacy evidence for the use of dienogest in this setting, the detailed review was provided within the meeting agenda pack. The information presented also included the estimated resource impact for dienogest, based on this, the resource impact of the submission is within the financial threshold that the Committee is authorised to approve.

- **Applicant's presentation**

The applicants and an Obstetric and Gynaecology Clinical Nurse Specialist (not an applicant) were in attendance to present this submission and field any questions. The applicants and presenters DoI's were noted.

The applicant confirmed that dienogest is considered an appropriate treatment option for the patient cohort outlined in the application. The intended criteria for use was clarified by the presenter; dienogest is aimed as a second line treatment after already established, conventional hormonal treatments and is an alternative treatment option to gonadotropin hormone-releasing hormone (GnRH) agonists such as Zoladex™.

The applicant also described the clinical scenarios where patients may prefer treatment with dienogest over a GnRH agonist and vice versa, this being a decision based on patient factors. The applicant noted the desired prescribing arrangements for dienogest as initiation and first prescription by the specialist team followed by transfer of prescribing to primary care.

- **IMOC discussion after departure of presenters**

Committee members discussed the application and members acknowledged that dienogest is suitable as a second line treatment option for the treatment of endometriosis related pain where analgesia and first line already established, conventional hormonal treatments have been ineffective. Committee members discussed the transfer of prescribing to primary care and noted that it would be useful for this to occur once the patient has been reviewed by the specialist, however Committee members accepted that the practilities of this would be difficult as specliast review is at 4 – 6 months after initiation, which could lead to medicines waste. Committee members noted that it would be useful to review outcome data for dienogest after a year of use.

The Committee agreed by consensus a category of Amber 2 (initiation and first prescription from the specialist team) alongside outcome data to be presented back to the Committee in 12 months (time limited recommendation).

ACTION: Formulary recommendation to be drafted and presented at next meeting
ACTION: Outcome data to be presented back to the Committee in 12 months

8. Formulary submission: Pitolisant (Wakix™) 4.5mg and 18mg tablets for the treatment of cataplexy within type 1 narcolepsy (narcolepsy with cataplexy):

This formulary submission originates from GSTT – Consultant in Sleep Medicine. The application requests the use of pitolisant as a second line treatment option for cataplexy in patients that do not already qualify for treatment for the management of their daytime sleepiness symptoms of narcolepsy. Pitolisant is intended to be used at a dose of 4.5mg to 36mg every morning. These doses are within the range for their licensed use in narcolepsy with or without cataplexy.

- **Evidence review**

The Formulary Pharmacist presented an overview of the efficacy evidence for the use of pitolisant in this setting, the detailed review was provided within the meeting agenda pack. The information presented also included the estimated resource impact for pitolisant, based on this, the resource impact of the submission is within the financial threshold that the Committee is authorised to approve. A draft updated version of the existing SEL pathway for the pharmacological management of cataplexy associated with narcolepsy was also provided within the meeting agenda pack to demonstrate where pitolisant would be placed in the treatment pathway.

- **Applicant's presentation**

The applicant was in attendance to present the submission and field any questions. The applicant's DoI was noted. The applicant confirmed that pitolisant is considered an appropriate treatment option for the patient cohort outlined in the application, which is for patients who have type 1 narcolepsy but their predominant symptom is cataplexy. The applicant clarified the intended criteria for use; pitolisant will be used as a second line treatment option if first line treatment options (clomipramine or venlafaxine) are ineffective or patients are intolerant. The applicant described that pitolisant is an alternative second line treatment option to sodium oxybate in this patient cohort. There is no clinical preference between pitolisant and sodium oxybate, although patients tend to prefer pitolisant due to the side effect and safety profile of sodium oxybate however, there is limited experience of use with pitolisant.

- **IMOC discussion after departure of presenters**

Committee members discussed the application and members acknowledged that pitolisant is suitable as a second line treatment option for the treatment of cataplexy within type 1 narcolepsy. However Committee members agreed it would be useful to review the number of patients initiated on pitolisant with controlled narcolepsy and cataplexy symptoms in 12 months as well as the overall number of patients managend with pitolisant in SEL for the various indications approved within the local formulary. As the updates to the pathway for the pharmacological management of cataplexy associated with

narcolepsy are minimal and manly reflects this formulary submission, the Committee agreed the updated pathway does not need to be consulted widely across SEL.

The Committee agreed by consensus a category of Red (hospital prescribing only) alongside outcome data to be presented back to the Committee in 12 months.

ACTION: Formulary recommendation to be drafted and presented at next meeting
ACTION: Updated pathway to be updated in line with discussions and presented at next meeting
ACTION: Outcome data to be presented back to the Committee in 12 months

9. i. For discussion: Draft treatment pathway following formulary applicationin October 2021 for various agents for the treatment of co-morbid insomnia in adult patients (off-label use)

ii. For approval: Formulary inclusion of melatonin for the licensed indication of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over for 13 weeks following discussion at the October 2021 MPRG meeting

The author was in attendance to present this item prior to wider consultation across SEL. The draft management of co-morbid insomnia pathway has been developed following initial discussions in October 2021, where formulary applications for a number of agents in this setting were considered.

As part of the discussions in October 2021, there was also a request to add melatonin to the local formulary for the licensed indication only (patients who are aged 55 or over for 13 weeks). The Committee is being asked to consider the approval of melatonin as a green categorised medication in the local formulary, this request will formalise the prescribing practice already in place locally for the licensed indication of melatonin in primary and secondary care.

Committee members provided feedback on the updated pathway. This included a comment regarding the management of transient and expected short term comorbid insomnia with zopiclone or zolpidem (Z drugs) after 3 months of treatment with melatonin, which implies a patient's insomnia is not "transient or short term". The author clarified Z drugs are generally used to manage transient and expected short term comorbid insomnia caused by a trigger to a patients comorbid insomnia, however the wording on the pathway can be updated to make this clear. Another comment was raised in relation to adding which treatment options are being proposed for transfer of prescribing to primary care within the pathway.

Committee members agreed the the draft management of co-morbid insomnia pathway was ready for wider consultation across SEL following updates to the pathway in line with discussions.

Committee members approved by consensus the formulary inclusion of melatonin within the local formulary as a green categorised medicine for its licensed indication.

ACTION: Melatonin to be added to the local formulary as a green categorised medicine for the licensed indication
ACTION: Authors to update pathway in line with discussions before it undergoes wider consultation.

10. Follow up data for the use of pitolisant to improve wakefulness and reduce excessive daytime sleepiness in adult patients with idiopathic hypersomnia

The author was in attendance to present follow up data on the use of a of pitolisant to improve wakefulness and reduce excessive daytime sleepiness in adult patients with idiopathic hypersomnia (IH) following a formulary approval in June 2021.Follow up data were requested at one year as part of the original formulary approval.

The author updated the Committee on patient numbers and outcomes data the detailed follow up data was provided within the meeting agenda pack, in summary:

- 43% of patients who have been referred to the sleep centre with IH for consideration for treatment with pitolisant have been initiated on pitolisant
- 12.5% of patients referred and initiated on pitolisnt for IH have stopped treatment due to adverse effects and 21% of patients have stopped treatment due to lack of efficacy
- Outcome data were available for approximately half of the patients initiated on treatment (as some patients had only recently started treatment); a 35% reduction on the Epworth Sleepiness Scale (ESS) was demonstrated in patients who responded to treatment and non-responders demonstrated no change in ESS
- The majority of patients who were concomitantly prescribed stimulant therapy and pitolisant were able to reduce the dose of the stimulant treatment or stop their stimulant

A comment was raised in regards to whether the specialist team viewed pitolisant as a valuable treatment option given approximately a third of the patient cohort stopped pitolisant. The author clarified that the safety profile of pitolisant is more favourable in comparison to other treatments such as stimulants and that it is a valuable option to have as part of the other treatment options available.

The Committee noted the follow up data report and agreed by consensus that it was acceptable to remove the time limit on the formulary recommendation.

ACTION: Formulary recommendation to be updated (removal of time limit)

11. Standing items

- Formulary submissions tracker

Noted.

- NICE Technology Appraisal Guidance Summary – ICS attributed medicines & NHSE/I commissioned NICE TAs:

The summary was noted and Red, Amber, Green, Grey (RAGG) categories were agreed by consensus

- RMOC update - for information

The Committee noted the next RMOC meeting is planned for 25th August 2022.

12. Any other business

No items raised.

IMOC dates for next 3 months

Date	Time	Venue
15th September 2022	2:00pm – 4:30pm	MS Teams
20th October 2022	2:00pm – 4:30pm	MS Teams
17th November 2022	2:00pm – 4:30pm	MS Teams