South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
Thursday 19th September 2pm to 4:30pm (Meeting held 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 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 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 for approval

- **New formulary recommendation 151 – Lyumjev® (fast-acting insulin lispro) 100 units/mL insulin for the treatment of diabetes mellitus in adults.**

The Committee were informed that comments had been received regarding minor formatting changes to the draft recommendation and a comment to include specific reference to the 100 unit/mL strength that had been requested in the formulary application. There were no further comments from members and the recommendation, pending the described changes, was approved by consensus.

- **Updated formulary recommendation 115 – Fiasp® (fast-acting insulin aspart)**

This recommendation was updated following the approval of the Lyumjev® formulary application at the last meeting, as an alternative fast-acting insulin. There were no comments from members and the updated recommendation was approved by members by consensus.

ACTION: Formulary recommendation 151 to be amended as discussed and submitted for IMOC Chair's ratification.

5. Formulary application for salicylic acid 10% and fluorouracil 0.5% solution (Actikerall®) for the management of recalcitrant warts (off-label)

This formulary submission originates from a GP with an extended role in community dermatology under Guy's and St Thomas' NHS Foundation Trust and is supported by the dermatology sub-group of the Committee. Actikerall® is a combination of 10% salicylic acid (SA) and fluorouracil (FU) 0.5% in a solution formulation currently licensed for the topical treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (grade I/II) in immunocompetent adult patients. This indication is formulary included in SEL with a "Red, Amber, Green, Grey" (RAGG) categorisation of Green. The application requests the use of Actikerall® as a second line treatment option after salicyclic acid. Actikerall® will be used as a 12-week treatment course for recalcitrant and highly symptomatic warts in adults and children, where previous treatments have failed or are inappropriate e.g. peri-ungual warts, cryotherapy in children, cryotherapy in richly pigmented skin, immuno-suppressed patients. The preparation is intended for use where there is a specific need to treat patients due to significant interference with daily living and where alternative topical treatments have been ineffective, are inappropriate or there is a particular concern about disease spread. Use in this setting is an off-label use for Actikerall®. The application requests a Green RAGG category for Actikerall® in adults and an Amber 1 RAGG category for paediatrics.

➢ 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 Actikerall® in this setting.

Cutaneous warts are common, benign, and usually self-limiting papillomas caused by infection with the human papillomavirus (HPV), usually occurring on the hands and soles of the feet. The general consensus regarding treatment of warts is that no treatment is required. However, the National Institute for Health and Care Excellence (NICE) clinical knowledge summary (CKS) for warts and verrucae acknowledge the potential benefits of treating warts. This view is also supported by the 2014 British Association of Dermatologists (BAD) guidelines. Additionally, the 2022 UK Primary Care Dermatology Society (PCDS) guidance acknowledges Actikerall® as an off-label treatment option available in intermediate/secondary care or through a GP experienced in treating warts. Topical salicylic acid (SA) treatment and/or cryotherapy with liquid nitrogen are the most common therapeutic interventions recommended for common and plantar warts and have the strongest evidence for efficacy. Other off-label treatments target enhancement of local immune response (e.g. imiquimod) and anti-proliferative therapy (e.g. topical fluorouracil (5-FU) 5% cream).

With respect to the evidence base, recommendations for salicylic acid treatment are based on expert opinion from BAD and weak evidence from a 2012 Cochrane review which found salicylic acid more effective than placebo at clearing cutaneous warts. Limited evidence from several randomised trials have demonstrated some benefits of topical 5-FU for cutaneous warts with cure rates around 50%. A systematic review of 8 randomised controlled trials (RCTs) assessing 5-FU-SA combination therapy identified a positive therapeutic effect across all the studies. Complete healing was recorded in 63.4% of common warts cases and 63% of plantar warts cases treated with the 5-FU-SA combination therapy, which demonstrated superiority over the 5-FU-free control arms. A smaller, retrospective observational study in periungual warts assessed the efficacy of 0.5% 5-FU/10% SA when employing conventional application methods versus a new application technique. Both methods achieved a 50% clearance rate of warts, however the new method of application demonstrated a significantly greater treatment response. Another small observational study using 0.5% 5-FU/10% SA reported complete resolution in 86% of patients with treatment resistant ungual warts, with 14% of patients reporting partial resolution. None of the study participants reported treatment side effects.

No new safety signals were identified from the evidence reviewed. The licensing study for actinic keratosis reported mainly mild or moderately intense adverse events. The summary of product characteristics (SPC) for Actikerall® lists erythema, inflammation, irritation, pain, and pruritis at application site as very common adverse reactions. Headache, skin exfoliation, and bleeding at application site are listed as common. As this application proposes administration in an identical way to the licensed use, no additional safety concerns are anticipated.

From a resource impact perspective, the resource impact of the submission is within the financial threshold delegated to the committee. As treatment with Actikerall® would only be considered if all other treatments fail or are considered inappropriate, this represents an additional cost. However, this is likely to be negligible as the availability of Actikerall® for this indication is anticipated to reduce the need for cryotherapy. This will result in a reduction of the associated staffing and cryotherapy clinic costs, thus creating time and cost savings across the healthcare system.

- **Applicants' presentation**

The applicant was in attendance to present and respond to questions from the committee. The applicant's declaration of interests were noted.

A query was raised regarding the arrangements for prescribing Actikerall® at Great Ormond Street hospital (GOSH), which is noted in the application form using Actikerall in this setting. The applicant noted that transfer to primary care would be unlikely as GOSH is a tertiary centre. Additionally, Actikerall® is of particular benefit in immunosuppressed patients in secondary care. The applicant agreed to follow this up. It was clarified by the applicant that based on experience, it is highly unusual for children to suffer from extremely persistent or symptomatic warts, especially with routine treatment. Therefore the cohort requiring treatment is likely to be small. The applicant confirmed that treatment is not being requested for cosmetic reasons. Treatment is intended for people with highly symptomatic warts that pose significant challenges (e.g. warts under nails or a substantial number of warts or painful warts interfering with activities of daily living). With respect to the dosing method, it was confirmed by

the applicant that the greatest efficacy has been demonstrated with daily application for 7 nights with occlusion, followed by removal and paring weekly, and this would be the chosen application.

In response to queries from members regarding the proposed RAGG category of Green in adults, the applicant agreed that an Amber 1 RAGG categorisation would be acceptable. However, the applicant also noted that as wart management already occurs in primary care, there would be minimal concerns regarding GP initiation. Members requested clarification regarding the intended place in therapy of Actikerall®, particularly in relation to cryotherapy within the draft proposed pathway included in the paperwork. Actikerall® would be used as a second line therapy after topical wart treatments and cryotherapy as third line. There are several financial, safety and training elements required to safely provide cryotherapy treatment. Additionally, it can have side-effects such as blistering, is labour and time intensive for practitioners and extremely intrusive for patients.

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

Members discussed the application and whether the use of Actikerall® in this setting would be better suited to an Amber 1 or Amber 2 categorisation for all patients. Most GPs would not treat warts, it was felt that the presentation of highly symptomatic warts was not routine in primary care and would require specialist input. Members also discussed how an Amber 1 category would provide primary care with an additional treatment to offer for patients. It was suggested that GPs already had familiarity with the individual components of Actikerall® and together with readily accessible dermatology advice and guidance, and national guidelines there was reasonable reassurance to support primary care initiation after a specialist has recommended it. Committee members approved by consensus the formulary application with an Amber 1 RAGG category in adults and children with recalcitrant warts. The approval is pending update, consultation and approval of the existing viral warts pathway to reflect Actikerall®. Until this is complete, Actikerall® in the management of recalcitrant warts remains non-formulary.

ACTION: Applicant to progress updates to the viral warts pathway to reflect the place in therapy of Actikerall®, including the Amber 1 status, for subsequent review and approval by the committee

6. Formulary application for betamethasone valerate 2.25mg plasters (Betesil® medicated plasters) and fludroxycortide 4 microgram/cm² tape for keloid and hypertrophic scars

The formulary applicant from the previous submission has also made this submission. The application requests the off-label use of betamethasone 2.25mg medicated plasters (Betesil®) and fludroxycortide 4 microgram/cm² tape as first line options for the treatment of symptomatic hypertrophic or keloid scars in adults as an alternative to clobetasol 0.1% cream used under an occlusive dressing. The application requests a Green RAGG categorisation for the use of Betesil® and fludroxycortide tape in these indications, for initiation of treatment by GPs in primary care prior to specialist dermatology service referral. Fludroxycortide tape is listed within the SEL adult Joint Medicines Formulary (JMF) for its licensed indication, which covers dermatoses but not hypertrophic scars. Betesil® tape is licensed for a maximum of 30 days under its licensed indication, which covers treatment of inflammatory skin disorders not responding to treatment with less potent corticosteroids.

- **Evidence Review**

The Formulary Pharmacist summarised 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 the requested products in this setting. Hypertrophic scars and keloids are fibroproliferative disorders that result from aberrant wound healing following trauma, surgery, or burns. The risk of keloid development appears to be highest in individuals with African or Asian ancestry. There are no NICE guidelines for the management of hypertrophic or keloid scars. Active treatment for hypertrophic or keloid scars initially involves topical steroids as first line treatment, followed by intralesional steroids, intralesional chemotherapeutic agents (e.g. 5-fluorouracil or bleomycin), surgical excision and radiation therapy in extreme cases. The PCDS recommend fludroxycortide tape and Betesil® plasters as specific formulations that might be helpful, especially as their formulation be beneficial as these adhesive, steroid-impregnated products can be

cut to size for their licensed indications. Guidance from the British Association of Aesthetic Plastic Surgeons also states that tape and plaster adhesive versions of steroids may be a preferred formulation for managing hypertrophic or keloid scars.

With respect to the evidence base, there are few clinical studies describing the use of either treatment in hypertrophic or keloid scars. For fludroxycortide, data are limited to small low quality case series, which found treatment was well tolerated and successful in reducing scar size. One small comparative study in 16 patients found Betesil® increased the speed of surgical scar healing after plastic surgery vs. usual care. The pivotal licensing study for Betesil® found it improved lesion clearance vs. non-occluded steroid cream application when used for the treatment of psoriasis. However, the recommendations in the PCDS guidance for the use of Betesil® and fludroxycortide tape appear to be on the pragmatic basis that topical steroid treatment is the routine approach for hypertrophic and keloid scars, and these adhesive formulations are likely to be helpful where continued exposure to locally applied steroid is desired.

With respect to safety, no serious adverse events were reported with the use of Betesil® plasters or fludroxycortide tape, and the evidence available does not suggest an increased rate of adverse effects when compared with topical steroid creams. All topical steroid products recommend that application of corticosteroids to large areas of the body for prolonged periods of time be avoided. However, the amount of topical corticosteroid used to treat hypertrophic or keloid scars is likely much lower that the amount recommended for licensed use, suggesting less incidence of side effects.

From a resource impact perspective, the resource impact of the submission is within the financial threshold delegated to the Committee. The application assumes that only 35% of the estimated financial impact would be increased costs, as the products are already in use. It is also expected that use of these formulations would likely be more cost effective than using steroid creams or ointments with dressings. The use of the plasters/tape will rely on patients being able to divide and cut patches appropriately prior to administration, which may not be possible in all instances.

- **Applicants' presentation**

The applicant was in attendance to present and respond to questions from the Committee. The applicant's declaration of interest was noted. The applicant outlined that fludroxycortide tape and Betesil® plaster already have established use in this setting and the request aims to formalise existing arrangements. It was confirmed by the applicant that both products are required on the formulary as the individual nature and size of the scars would determine which product is selected. Additionally, it would be useful to have an alternative option during supply shortages. Members highlighted that Betesil® is licensed for 30 days use for its licensed indication, whereas in keloid and hypertrophic scars, the planned use would be for 12 weeks and queried the rationale for the longer period of use. The applicant responded that the nature of keloids require a potent topical steroid treatment. It is accepted practice for keloids to be treated with a three month course of potent topical steroids (e.g. Dermovate®). This application reflects the expectation that use of Betesil® for the same duration will be as effective, with the main adverse effect and limiting factor of treatment being hypopigmentation.
The clinical criteria to support decision making on whether the use of a steroid based tape/plaster is warranted include scar pain and itching, which are the most common symptoms that trigger specialist referral. Treatment is not initiated solely on cosmetic grounds. Occasionally patients may present with significant psychological symptoms, however these patients are usually not suitable for topical treatment. The applicant also advised that the draft treatment pathway for keloid and hypertrophic scars included in the meeting paperwork is part of a guideline developed by Trust dermatology and plastics clinicians through the now disbanded dermatology network. It was agreed that the pathway will need review and approval via the IMOC, once it is finalised, to ensure medicines governance.

With respect to patient numbers, the applicant advised that it is anticipated patient numbers may increase by 35% based on the unmet patient need and as a result of an ongoing activities to promote best practice within GP practices. However, accurate monitoring of patient numbers will be difficult due to capacity issues within the clinics. A subsequent query was raised regarding how outcomes will be monitored to demonstrate value in the longer term. In response, it was proposed that one option may be to monitor the number of re-attendances for the same complaint or measure the number of referrals

to specialist dermatology services. A comment was also added by the ICB lead for the dermatology pathway group that changes in how the community dermatology service is commissioned in addition to other factors such as the significant delay in referral wait times and variation in service provider at borough level have made monitoring service outcomes challenging. The possibility of anecdotal monitoring has been explored. Prescribing rates could be monitored through the dermatology sub-group. This aspect will be further discussed through the dermatology sub-group. It was noted that in some cases, extended treatment courses may be required with the extended courses being supplied by primary care due to the current longer wait time for referral to community dermatology services. However, whilst extending treatment beyond three months is new for community services, it is within the six month treatment period that consultant dermatologists deem safe. Criteria for extended treatment will be made clear in the treatment pathway.

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

Members discussed the application and whether the use of Betesil® plasters and fludroxycortide tape in this setting would be better suited to an Amber 1 or Amber 2 categorisation. It was noted that the cohort would be small and whilst the applicant is a GP with a specialist interest in dermatology, most primary care prescribers would not find initiating in primary care under a Green RAGG category appropriate. Members felt an Amber 1 categorisation was of greater benefit to both primary care prescribers and patients, as advice and guidance could be sought on whether to initiate.

Members also discussed that the content of the draft keloid and hypertrophic scar pathway would require formal review and ratification prior to formulary inclusion so that the treatment pathway is clear. The committee agreed by consensus that an Amber 1 category was appropriate for use of Betesil® medicated plasters and fludroxycortide 4 microgram/cm^2 tape for the treatment of hypertrophic and keloid scars in adults, pending approval of the pathway. Until the pathway is approved, these products remain non-formulary in this setting.

ACTION: Applicant to progress the pathway for keloid and hypertrophic scar management

7. World Antimicrobial Awareness Week 2023 feedback from engagement activities

The ICB lead for antimicrobial stewardship (AMS) was in attendance to provide an overview of the activities undertaken throughout SEL during World Antimicrobial Awareness Week (WAAW) in 2023. The presenter invited any suggestions to inform planning for the 2024 WAAW. Members noted the update and thanked the presenter for sharing the activities undertaken.

8. Biosimilar ustekinumab - formulary status

Biosimilar versions of ustekinumab are now available and represent the largest biosimilar opportunity identified within the NHS this year. Nationally, data from the Specialist Pharmacy Services (SPS) indicates £245 million was spent on ustekinumab between August 2023 – July 2024 across England. Ustekinumab is predominantly used for gastroenterology and dermatology indications, with some small usage in rheumatology. The acute trusts within SEL have plans in place to support implementation of the biosimilar, however it has been recognised that the adult joint medicines formulary (JMF) needs to reflect the availability of the biosimilar versions. In line with the introduction of previous biosimilar products, it is proposed that the formulary entry for ustekinumab will be amended to include a generic statement advising that biosimilars are available and they must be prescribed by brand. As the originator product is already included in the formulary, it was proposed that a full formulary application process would not be required. This is in line with other generic medicines which do not routinely require full formulary applications if the originator branded product is already on the formulary.

The Committee were advised that the current licensing for ustekinumab biosimilars does not include ulcerative colitis (UC) so patients with this condition are currently not eligible for initiation or transition to the biosimilar version. It was noted that the inclusion of biosimilars that are not hospital only and can be prescribed in community or primary care (such as biosimilar insulins) may require additional resources and discussion at the IMOC, to support primary care implementation.

A cross-specialty planning meeting has taken place with the local acute trust leads to discuss their implementation plans for biosimilar ustekinumab, including consideration of capacity issues and financial flows. There will be ongoing discussion across the Integrated Care System (ICS) during implementation and a follow up meeting is being planned. It was noted that for the formulary entry for infliximab, there is a separate formulary recommendation that stipulates certain brands and since this was published, there are now a number of infliximab biosimilars available. It was noted that infliximab was the first biosimilar to be introduced and underwent a full formulary process. However, with time this has evolved and formulary recommendations have not been drafted to subsequent biosimilar products. The infliximab recommendation will be reviewed and may need to be retired.

The Committee agreed by consensus for the amendment of the ustekinumab formulary entry to include the biosimilar.

ACTION: Formulary team to update ustekinumab formulary entry regarding biosimilars

9. Follow up: Formulary application for pyridostigmine in adults for the treatment of postural tachycardia syndrome (PoTS)

The original formulary applicant (a specialist Consultant Cardiologist at King's College Hospital (KCH) was in in attendance to present this item, supported by the Formulary Pharmacist. This is in follow up to discussions at the July 2024 IMOC meeting in relation to the formulary application for use of pyridostigmine in this setting. The notes extract from the July 2024 IMOC meeting was included to remind members of the original discussions. The Committee had requested clarity on a number of aspects at the July IMOC meeting, including the exact ongoing monitoring required in primary care.

The presenters confirmed that patients would self-monitor their blood pressure (BP) and heart rate (HR), with regular reporting to the KCH arrythmia nurses and an annual review by the GP. The requirement for blood tests in primary care was also clarified by the applicant. Primary care prescribers will be advised that liver function tests (LFTs) and urea & electrolytes (U&E's) are required annually. In terms of supply after the initial 6-week period, it was confirmed that medications for the treatment of PoTS are titrated over six weeks, after which they are only continued if there has been a positive response to treatment. At six weeks, the patients will be reviewed by the arrhythmia nurses and if the decision is for continuation of treatment, the transfer of care paperwork will be sent to the GP and a further supply of medication issued by the hospital. A draft pathway has also been developed as a potential primary care resource based on medication information currently given to patients who attend the specialist clinic. Committee members agreed for the pathway /algorithm approach to be progressed.

Members were requested to consider the original formulary request, which was for an Amber 3 RAGG categorisation and asked to consider a decision based on the additional information provided. Committee members were satisfied with the information provided and approved, by consensus, an Amber 3 RAGG category. This is pending development of the Transfer of Prescribing proforma and the pathway, which will need to be routed through the cardiovascular sub-group. Until the pathway and transfer of prescribing documentation is approved, pyridostigmine remains non-formulary for use in PoTS in adults.

ACTION: Authors to progress final drafts of the pathway and transfer of prescribing documents via the CVD sub-group leads followed by broader IMOC consultation

10. Formulary requests relating to the use of melatonin in sleep disorders/insomnia

(i) Request to recategorise melatonin from Amber 3 to Amber 2 in children and young people aged less than 18 years old with sleep disturbance and insomnia

(ii) Request to include a licensed melatonin 1mg/ml oral solution (Ceyesto®) in adults and paediatrics to replace the unlicensed preparation (Kidmel®)

The applicants (clinicians from GSTT and a Pharmacist Lead from the South London and Maudsley hospital) were in attendance to present this item supported by the Lead Paediatric Formulary Pharmacist.

(i) Request to recategorise melatonin from Amber 3 to Amber 2 in children and young people aged less than 18 years old with sleep disturbance and insomnia

It has been recognised that many specialist clinics involved in the management of sleep disturbance in young people have struggled with capacity issues. Recent prescribing data has shown that primary prescribing of melatonin in children is significantly greater than hospital prescribing, suggesting prescribers in primary care may be initiating melatonin therapy. Minimal clinical impact is expected for primary care from this request as it is proposed that patients be discharged from specialist care once they have had one follow up after commencing treatment and are established on the appropriate effective dose. Where children are identified as more complex, these patients would remain under specialist care and the recategorisation would also support increasing clinic capacity for these ongoing reviews. It is also recognised that a more relevant prescribing pathway and arrangements for continued prescribing in primary care are needed to reflect current practice. Adaflex® has been included within the proposal as it was agreed in principle for formulary inclusion in the paediatric formulary at the March 2023 IMOC meeting, pending an action to update to the existing prescribing pathway and shared care guideline for melatonin. This action was paused to enable this request to recategorise melatonin to be developed and progressed.

(ii) Request to include a licensed melatonin 1mg/ml oral solution (Ceyesto®) in adults and paediatrics to replace the unlicensed preparation (Kidmel®)

The Committee were advised that whilst several licensed melatonin liquids are available for procurement, historical concerns regarding excipients led to the unlicensed Kidmel® preparation being recommended for use across SEL. However, the licensed product, Ceyesto®, has a more favourable excipient profile and the request is proposing to include Ceyesto® within the adult and paediatric formularies as the recommended product.

Members discussed the requests and a query was raised regarding how complex patients are defined and whether the updated melatonin prescribing pathway will make this clear. The presenters responded that these patients will usually have an underlying neurodevelopmental condition, rather than only an autism diagnosis and further assessment in a tertiary centre is required. This could be attention deficit hyperactivity disorder (ADHD) plus another genetic diagnosis where previous behavioural or pharmacological interventions have failed. This aspect will be included in the updated pathway.

In response to a query on recommendations to support review and deprescribing of melatonin in primary care, the presenters confirmed that clinicians do advise for children on long term melatonin to take at least one annual 'melatonin break' ideally during the school holidays. Clear guidance on titration and melatonin breaks are supplied in clinic letters and provided to parents/carers to support this.

The presenters also confirmed that the existing guidance could be updated to support generic prescribing of the 2mg melatonin modified release tablet, however in this cohort of patients, there may be several individual patient factors that will have determined the choice of melatonin product. Therefore, careful consideration is required as it may not be appropriate to switch to a generic product in all cases, especially if a child is stabilised on a particular brand. A comment was raised regarding the need for individual management plans for patients prescribed melatonin. It was noted that the individual management plans were a requirement under the Amber 2 RAGG categorisation. A template management plan letter could be considered as part of the prescribing pathway review to ensure information from all providers is consistent across SEL.

With respect to whether the request is within the financial limits delegated to the committee for approval, the presenters advised that patient numbers are unlikely to increase but this can be clarified outside of the meeting.
Post meeting note: *It was confirmed that Ceyesto® would replace Kidmel® in the existing eligible patient cohort. Additionally, it is less costly than prescribing the unlicensed Kidmel® and other unlicensed specials liquids, therefore Ceyesto® could be cost-saving. Prescribing would need to be by brand in order for the most cost-effective preparation to be dispensed. The request is therefore within the financial thresholds delegated to the committee.*

Committee members approved by consensus the request to recategorise melatonin from Amber 3 to Amber 2 in children and young people aged less than 18 years old with sleep disturbance and insomnia. Members agreed the existing shared care guideline could be withdrawn once a review of the pathway has been completed and approved by the committee. Committee members also approved by consensus the formulary request to include Ceyesto® in the adult and paediatric formulary. Kidmel® will be removed from the paediatric formulary. It was also agreed by consensus that Adaflex® will be included as Amber 2, following the discussions at this meeting and the formulary application considered in March 2023, pending updates to the melatonin prescribing pathway.

Post meeting note: *The Adaflex® approval covers use as per the licensed indication (as per the original formulary application from March 2023): Treatment of insomnia in children and adolescents aged 6-17 years with ADHD where sleep hygiene measures have been insufficient.*

ACTION: Leads to progress updates to the melatonin prescribing pathway in line with discussions, for future review and approval through the committee

11. Formulary requests for Continuous Glucose Monitoring (CGM) devices for use in Type 1 diabetes mellitus:
- **(i) Dexcom One + (adults)**
- **(ii) GlucoRx Aidex transmitter (adults)**
- **(iii) Freestyle libre 3 (adults and children & young people)**

A Consultant Diabetologist from GSTT was in attendance to present this item with support from the Lead Pharmacist for Medicines Optimisation in the ICB.

(i) Dexcom One + (adults)

The manufacturers of Dexcom One, which is available on the formulary for Type 1 diabetes for adult patients who cannot tolerate Freestyle Libre devices, have released newer sensors including Dexcom One +. This request is to replace Dexcom One with Dexcom One + on the formulary as the new device has significant advantages including a smaller size, (to aid application), a significantly shorter warm up period of (30 minutes compared to 2 hours) and greater accuracy. The numbers of adult patients in SEL using Dexcom One are small and these patients would be switched to Dexcom One + gradually via their routine hospital appointments. Where new Type 1 diabetes patients are eligible for Dexcom devices, they will be offered Dexcom One +. With respect to the resource impact, the cost is a substitute cost for those currently on Dexcom One sensors so no additional impact is expected. Additional costs for new patients are therefore estimated to be within the previously overall predicted costs that were escalated to and approved by the SEL finance committee. The overall resource impact has therefore been previously approved.

(ii) GlucoRx Aidex transmitter (adults)

GlucoRx Aidex sensors are already included in the formulary for a small number of patients but require an additional transmitter to transmit data to the smartphone app. The transmitter was previously provided by the manufacturer and replaced every four years. The manufacturer have since advised that the transmitters will need to be supplied via prescription as they are now included in the Drug Tariff as devices that can be prescribed on FP10 prescriptions. With respect to the resource impact, it was noted the cost of a transmitter is £19.99 which equates to approximately £4.99 per year. The patient numbers using this device are low and the cost impact is therefore expected to be low. The presenters clarified that since the meeting paperwork was circulated, it has been identified that the company has reduced the price of the sensors, further reducing the cost impact. The resource impact is therefore within the financial threshold delegated to the Committee.

(iii) Freestyle libre 3 (adults and children & young people)

Freestyle Libre 3 is currently in use within SEL, but less frequently used than Freestyle Libre 2. It is ordered through the NHS Supply Chain via the hospitals then delivered by NHS Supply Chain to the patient. It is now available for prescribing via FP10 prescription in primary care as it has been added to the Drug Tariff. This is advantageous to the patient as this will align supply with their other medications. There is also a system saving when supplying Freestyle Libre 3 by prescription compared to using NHS

Supply Chain. Freestyle Libre 3 is being requested for inclusion in the formulary because it is compatible with a specific insulin pump used in a select group of people within SEL. With respect to the resource impact, no additional system costs are anticipated with switching from NHS Supply Chain supply to FP10 prescribing. Additional costs for new adult patients are estimated to be within the previously overall predicted costs that were escalated to and approved by the SEL finance committee. The overall resource impact for adults has therefore been previously approved. It was noted that approval of the children and young people's pathway (CYP) for CGM is pending as the final documentation for escalation to the finance committee is awaited from the authors. As the financial impact of the CYP pathway exceeded the financial threshold delegated to the committee, escalation to the finance committee was required following previous presentation at the IMOC.

In response to a query from members, the Committee were advised that all the CGM applications are requesting an Amber 1 RAGG categorisation for adults with Type 1 diabetes. The request for Freestyle Libre 3 in children & young people is for an Amber 2 RAGG category. The risk of mis-selection of Freestyle Libre 2 and 3 in primary care was noted. The presenters acknowledged that given the rapid development rate of new devices, clear information for patients, pharmacists and GPs is especially important and would be useful. Tools such as Optimise Rx can be used to provide messages at the point of prescribing. It was noted that the adult CGM guidance for SEL is currently undergoing review to reflect the recently added CGM devices.

Committee members approved by consensus the request to include Dexcom One +, Freestyle Libre 3 and the GlucoRx Aidex transmitters for adults with Type 1 diabetes in the adult formulary as Amber 1. Committee members agreed by consensus that Freestyle Libre 3 for use in CYP could only be approved on a clinical basis in principle as Amber 2. Escalation to the finance committee is pending for the CYP pathway, until this is complete, Freestyle Libre 3 remains non-formulary in CYP with Type 1 diabetes.

ACTION: Dexcom One +, Freestyle Libre 3 and the GlucoRx Aidex transmitter to be added to the SEL adult formulary as Amber 1, with information included that the CGM guidance documentation is under review to incorporate this new device. Paediatric formulary inclusion of Freestyle Libre 3 as Amber 2 to be completed once the paediatric CGM guidance is signed off

12. Standing items/Items for information only

- Formulary submissions tracker
  Noted.
- NICE 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. The RAGG categories for the following will require further discussion:
- Vibegron for treating symptoms of overactive bladder syndrome
- Linzagolix for treating moderate to severe symptoms of uterine fibroids
- Relugolix for treating hormone-sensitive prostate cancer

- For information and noting:
- RMOC update – nil for this meeting, RMOC meetings are paused.
- Adult and paediatric formulary updates – noted by Committee members.
- Low molecular weight heparin (LMWH) prescribing communications – noted by Committee members.

13. Any other business
Nil items raised.

IMOC dates for next 3 months

Date	Time	Venue
Thursday 17th October	2pm – 4.30pm	MS Teams
Thursday 21st November	2pm – 4.30pm	MS Teams
Thursday 19th December	2pm – 4:30pm	Hybrid – MS Teams and face-to-face