South East London Integrated Medicines Optimisation Committee (SEL IMOC) Meeting
21st August 2025 (Hybrid meeting)
Final Minutes

1. Welcome, introductions and apologies

The Chair welcomed attendees to the meeting. Apologies and observers were noted, and the meeting was noted to be quorate.

2. Conflict of interests – declarations and DOI refresh

The Chair asked that any conflicts of interest with the meeting agenda be declared and that any outstanding declarations be returned.

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

The minutes and detailed action notes were accepted as an accurate record of the meeting subject to the correction of minor typographical errors. The addition of a post meeting note to the June 2025 IMOC action notes and minutes was noted at the July 2025 IMOC meeting in relation to the formulary inclusion of Vivaire® as green for the management of COPD. However, respiratory leads have subsequently advised that beclometasone/formoterol preparations such as Vivaire® are no longer recommended locally for the management of COPD. In line with this, the post meeting note will be removed from the June 2025 IMOC action notes and minutes.

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

4. Xonvea® (doxylamine succinate 10mg/pyridoxine hydrochloride 10mg) for the treatment of hyperemesis gravidarum (HG) – outcome data and related formulary requests

The applicants were in attendance following the formulary application approval in 2022 which requested the presentation of outcome data for the use of Xonvea® in this setting.

~~i.~~ Outcome data relating to formulary recommendation 131- Xonvea® for treatment of nausea and vomiting in pregnancy

Across SEL in 2022/23 majority of patients were initiated on Xonvea® in line with the formulary recommendation, with just under two-thirds of patients experiencing an improvement in nausea symptoms and no hospital admissions for hyperemesis since starting Xonvea®. A small proportion of patients (~ a fifth) experienced no improvement in symptoms with Xonvea® . No adverse effects were observed with the use of Xonvea® in this setting. The original application estimated a greater number of patients may be eligible for treatment with Xonvea® in comparison to the number of patients noted within the outcome data for 2022/23, however based on the increase in spend observed in primary care since 2022/23, the use of Xonvea® in this setting is growing.

Committee members noted the outcome data and agreed by consensus to remove the time limit associated with the formulary approval.

ii. Formulary requests:

- **Change Xonvea® from 3rd line to 1st line for the treatment of nausea and vomiting in pregnancy and use as pre-emptive management of severe HG**
- **Historical addition of cyclizine & prochlorperazine (first line) and ondansetron & metoclopramide (second line) for the treatment of nausea and vomiting in pregnancy and pre-emptive treatment of HG (off-label) as amber 2**

Committee members considered the request to move Xonvea® from a third line treatment option for the management of nausea and vomiting (N&V) in pregnancy to a first line treatment option alongside cyclizine and prochlorperazine. This is in line with the recently updated national guidance on N&V and hyperemesis gravidarum (HG) in pregnancy published by the Royal College of Obstetricians and Gynaecologists (RCOG). The RCOG advocates for the use of Xonvea® as a first

line antiemetic in women with N&V in pregnancy/HG due to Xonvea® being the only licensed preparation in this setting and the strength of evidence supporting its use in this setting. The current Red, Amber, Green (RAG) category is Amber 2 *(specialist initiation).* From a cost perspective, this formulary request is within the financial threshold delegated to the committee.

A formulary request for the historical addition of cyclizine and prochlorperazine (off-label) as first line options and ondansetron and metoclopramide (off-label) as second line options for the treatment of N&V in pregnancy/HG was also considered by the committee. The use of cyclizine, prochlorperazine, ondansetron and metoclopramide for the treatment of N&V in pregnancy/HG is established practice locally in both primary and secondary care and is in line with RCOG guidance. It is not expected that the historical addition of these treatments to the formulary will have a cost impact, as the use of these treatments is established practice and the addition to the formulary is not expected to affect prescribing patterns.

In line with the recently updated RCOG guidance on N&V in pregnancy, committee members were requested to consider the off-label use of Xonvea®**,** cyclizine, prochlorperazine, ondansetron and metoclopramide for the pre-emptive treatment of HG in women who have experienced severe HG in previous pregnancies.

The Formulary Pharmacist provided a brief overview of the evidence to support this formulary request. The main evidence is from a Canadian randomised controlled trial (RCT) which investigated whether starting Xonvea® pre-emptively in women with a history of severe nausea and vomiting or hyperemesis gravidarum could reduce recurrence. The study found that pre-emptive treatment significantly lowered the rate of hyperemesis, reduced the number of women with severe "Pregnancy-Unique Quantification of Emesis" (PUQE) scores in early pregnancy, and increased the likelihood of symptoms resolving before labour, without a large increase in overall medication use. The authors concluded that early use of antiemetics may help prevent severe symptoms by avoiding complications such as metabolic disturbance and dehydration.

From a cost perspective, the pre-emptive use of anti-emetics for severe HG is within the financial threshold delegated to the committee.

A query was raised in relation to the safety of Xonvea® in pregnancy as it is a relatively new anti-emetic used in this setting and what advice can be provided to patients to provide reassurance Xonvea® is safe in pregnancy. The presenter clarified that Xonvea® is the only licensed treatment option for N&V in pregnancy. Xonvea® has been proven to be safe and effective through its licensing approval process and has been used in millions of pregnant women worldwide.

Clarification was sought in relation to how clinicians will decide between cyclizine, prochlorperazine and Xonvea® if all treatment options are suitable for a patient. The presenter confirmed that whilst there is no preference, it is likely the clinician will select the treatment they are most familiar with. The intention is that the treatments are available equally. Within secondary care Xonvea® is often used first line ahead of cyclizine and prochlorperazine due to the use of Xonvea® pre-emptively in women who have previously experienced severe HG in previous pregnancies.

In terms of benefits to the local health economy, the presenter explained that the use of Xonvea® first line for HG would help to prevent emergency hospital admissions, consequences from the mental health impact caused by severe HG (including suicide) and admissions to the obstetrics and gynaecology ward. Members suggested increased education for primary care clinicians on the treatment and pre-emptive treatment of HG would be helpful. Many primary care clinicians are not familiar with Xonvea®, and it appears to be a beneficial treatment in this setting, especially as the only licensed treatment option. In line with this, members debated whether the RAG category for Xonvea® in HG may be more appropriate as Green as opposed to Amber 2 for use in HG in the first pregnancy. The Amber 2 rating may be a barrier to patient access and could create a delay to treatment of severe HG. The presenter confirmed there are updated resources available to support primary care clinicians with the management of HG which includes a treatment algorithm developed for primary care within the RCOG guidance. This primary care treatment algorithm has also been reflected within NICE Clinical Knowledge Summaries (CKS) topic on N&V in pregnancy.

With respect to pre-emptive treatment, committee members felt more comfortable that this is on a specialist's recommendation, especially given the off-label nature. This would also help enable choice of the best medication for HG in subsequent pregnancies.

A comment was raised in relation to the SEL adult JMF entries being clear regarding the place in therapy of all treatment options available for the treatment and pre-emptive treatment of HG if approved, separating out the off-label use from the licensed use.

Committee members approved the following by consensus:

- The change in the place in therapy of Xonvea® for the treatment of HG from third line to first line and re-categorise Xonvea® in this setting from Amber 2 (specialist initiation) to Green (initiation in primary or secondary care)
- The historical addition of cyclizine and prochlorperazine (off-label) as first line options and ondansetron & metoclopramide (off-label) as second line options for the treatment of HG as Green.
- Formulary inclusion of Xonvea®, cyclizine, prochlorperazine, ondansetron and metoclopramide (off-label) for the pre-emptive treatment of severe HG as Amber 1 (initiation in primary care on the advice of a specialist).

ACTION: Formulary recommendation for Xonvea® to be updated and presented at a future meeting for approval
ACTION: SEL adult JMF formulary entry for Xonvea® to be updated outlining change in place in therapy from third line to first line in HG and recategorisation from Amber 2 to Green
ACTION: Cyclizine and prochlorperazine to be added to the SEL adult JMF as first line treatment (off-label) for HG as Green
ACTION: Ondansetron and metoclopramide to be added to the SEL adult JMF as second line treatments (off-label) for HG as Green
ACTION: Xonvea®, cyclizine, prochlorperazine, ondansetron and metoclopramide to be added to the SEL adult JMF for the pre-emptive treatment of severe HG (off-label) as Amber 1

5. Updated primary care migraine treatment pathway & associated cost modelling

Members of the headache & migraine sub-group were in attendance to present this item. The updated primary care migraine treatment pathway has been through IMOC consultation and approved via the headache and migraine sub-group.

The main updates to the pathway include:

- Addition of rimegepant for the acute treatment of migraine in line with NICE Technology Appraisal (TA) 919 alongside a request to recategorise rimegepant from interim Red (hospital only) to Green.
- Recategorisation of topiramate from Amber 1 to Amber 2 for the prevention of migraine in line with the recent Medicines and Healthcare products Regulatory Agency (MHRA) mandated pregnancy prevention programme (PPP) for all women of childbearing potential.
- Caution noted regarding prescribing propranolol in patients with co-existing depression and the possible increased risk of self-harm.

The presenters highlighted the benefits associated with rimegepant in comparison to triptans, noting that triptans' vasoconstrictive effects limit their use in patients with conditions such as myocardial infarction (MI), stroke, hypertension, and Raynaud's. However, as rimegepant is not a vasoconstrictor and exhibits its mode of action via vasodilation, rimegepant is a safer treatment option in these patient cohorts. Additionally, rimegepant is not associated with medication overuse which can be an issue with triptans when taken on more than two days a week.

The presenters provided rationale in relation to the recategorisation of rimegepant from interim Red to Green. Rimegepant for the acute treatment of migraine had been categorised as interim Red to enable its incorporation within the primary care migraine treatment pathway. There are low safety

concerns with rimegepant especially in comparison to triptans. The presenters acknowledged there may be some primary care clinicians unfamiliar with rimegepant initially, however advice and guidance is available to support primary care clinicians when initiating rimegepant for the first time despite the Green categorisation.

From a cost perspective, the addition of rimegepant for the acute treatment of migraine as Green to the primary care migraine treatment pathway is within the financial threshold delegated to the committee based on the NICE costing template. The costs noted are additional costs to the health economy and do not account for patients who would require direct treatment with rimegepant due to contraindications/intolerances to triptans .

The cost of rimegepant was raised in relation to triptans, noting that rimegepant is considerably more expensive than triptans and whether there is potential for waste when the medicine is initially started as patients are to be provided with 8 tablets. The presenter clarified the in line with feedback received, the guideline will be updated to recommend the prescribing of 4 tablets on initiation of rimegepant as opposed to 8 tablets, to help reduce the cost and potential wastage associated with patients in whom rimegepant is ineffective. This will be updated within the pathway.

A query was raised regarding the proportion of patients who will be unable to be treated with a triptan (contraindication) or have side effects to triptans and whether it is possible to estimate the cost impact of these. The presenter explained the proportion of patients who may fall into this category is challenging to estimate but it will be a small patient cohort. It was noted that the aim of treatment in this patient cohort would be to initially optimise preventative treatment where possible, for example, in patients who experience more than 15 days a month of migraine.

GP committee members raised the importance of education in primary care relating to the initiation of rimegepant to support prescribing in primary care. The presenter confirmed educational webinars are being planned to support the implementation of the updated pathway. The webinar will have a particular focus on how best to optimise the acute management of migraine with triptans as opposed to focusing on the initiation of rimegepant in place of triptans.

Committee members approved the following by consensus:

- Updated primary care migraine treatment pathway
- Recategorisation of rimegepant for the acute treatment of migraine from interim Red to Green
- Recategorisation of topiramate for the preventative treatment of migraine from Amber 1 to Amber 2

ACTION: Updated migraine treatment pathway to be updated in line with discussions and progressed for ratification via IMOC Chair's action
ACTION: Rimegepant to be recategorised from Red to Green within the SEL JMF for the acute treatment of migraine once the pathway is approved
ACTION: Topiramate to be recategorised from Amber 1 to Amber 2 within the SEL JMF for the preventive treatment of migraine once the pathway is approved

6. Updated dermatology pathways, outcomes, and monitoring framework & associated documents

The applicants were in attendance to present this item alongside SEL Integrated Care Board (ICB) Medicines Optimisation Leads for the dermatology subgroup. The updated psoriasis pathway, atopic dermatitis pathway and dermatology pathway outcomes and monitoring framework 2025/26 have been reviewed and approved via the dermatology sub-group.

i. Updated psoriasis pathway

The updated psoriasis pathway has been reviewed and approved via the dermatology sub-group. The main updates to the psoriasis pathway were summarised within the paperwork and include:

- Addition of spesolimab as a first line licensed treatment option for treating flares of generalised pustular psoriasis (GPP) in line with NICE TA 1070, including a new GPP treatment algorithm

- Addition of ustekinumab biosimilar as a first line treatment option and subsequent removal of the reference product
- Dose escalation of bimekizumab in people with plaque psoriasis who weigh less than 120kg (off-label)

From a cost perspective, the addition of spesolimab for treating GPP flares is within the financial threshold delegated to the committee based on the NICE resource impact report. The cost estimations do not model for subsequent doses beyond two doses, due to current limited information to inform redosing frequency in this rare patient cohort; however, patient numbers and dosing will be monitored via the outcomes and monitoring framework associated with the psoriasis pathway.

Committee members were requested to consider a request for dose escalated bimekizumab for plaque psoriasis in patients weighing less than 120kg (off-label). In line with the licence, patients who are over 120kg may be dose escalated to 320mg every 4 weeks if they do not achieve complete skin clearance at week 16 as per the product license. An unmet clinical need has been identified for a small cohort of complex psoriasis patients who weigh less than 120kg, have failed multiple treatment options as such patients may benefit from dose escalated bimekizumab, which is off-label. Patients would be considered for bimekizumab dose escalation via a multidisciplinary team where patients must meet set criteria.

From a safety perspective, there is reassuring evidence associated with bimekizumab at 320mg every 4 weeks as this is the standard licensed dose used in the management of hidradenitis suppurativa irrespective of body weight. From a cost perspective, based on the patient numbers estimated, the use of dose escalated bimekizumab is within the financial threshold delegated to the committee.

A query was raised in relation to whether most patients will respond to treatment with spesolimab or whether patients will still require access to the off-label treatments available for the management of GPP. The presenter clarified that as GPP is rare with small patient numbers, the availability of real-world data for the use of spesolimab is limited. Subsequently, the long-term response for spesolimab is not yet known and some patients may still require the use of the existing off-label treatments available for GPP.

A query was raised regarding the comment in the summary provided that the administration of spesolimab will be via inpatient appointments as opposed to via day case units/infusion suites and what the service plans are to review this arrangement. The presenter confirmed this is currently under review and service delivery should enable the administration of spesolimab via rapid access infusion clinics.

ii. Updated atopic dermatitis pathway

The updated atopic dermatitis (AD) pathway has been reviewed and approved via the dermatology sub-group. The main update to the pathway is the inclusion of nemolizumab for treating moderate to severe AD in people aged 12 years and over in line with NICE TA 1077. Nemolizumab is an additional treatment option in this setting alongside dupilumab, tralokinumab and lebrikizumab. Nemolizumab targets the interleukin-31 (IL-31) pathway and is not associated with ocular surface disease and may be beneficial as a second- or third-line treatment option in patients with a history of ocular surface disease, where itch is the predominant symptoms driving their disease and in those where a reduced dosing frequency of every 8 weeks is preferred.

From a cost perspective, the presenters confirmed that the cost presented is a substitution cost not an additional cost. This is because nemolizumab is a further treatment option against other treatments already NICE approved in this setting and priced similarly in line with the commercial price arrangement. Therefore the inclusion of nemolizumab is within the financial threshold delegated to the committee. The use of nemolizumab locally will be monitored using the atopic dermatitis monitoring framework in line with other biologic therapies.

iii. Dermatology pathway outcomes and monitoring framework

A new dermatology pathway outcomes and monitoring framework combining the individual psoriasis and AD pathway outcomes and monitoring frameworks has been developed and also includes audits associated with the local alopecia pathway. The new dermatology pathway outcomes and monitoring framework has been approved via the dermatology sub-group. The main updates to the audits within the dermatology pathway outcomes and monitoring framework includes:

- *Psoriasis*: patient experience surveys have been removed as they are not currently routinely utilised, however this will be reviewed at the next update
- *AD*: Audits have been updated to include all the new biologic therapies and JAK inhibitors.
- Severe alopecia: New audit focussed on the first 12 months of specialist care for all new patients with alopecia.

Committee members approved the following by consensus:
- Updated psoriasis pathway pending updates to the pathway in line with the discussion
- Bimekizumab dose escalation in people equal to or less than 120kg with complex plaque psoriasis
- Updated atopic dermatitis pathway
- Dermatology pathway outcomes and monitoring framework 2025/26

ACTION: Psoriasis pathway to be updated in line with discussions and progressed for ratification via IMOC Chair's approval

7. SEL primary care dermatology guidelines evaluation summary

The author was in attendance to present this item which is an evaluation summary from a survey shared with local primary care clinicians to evaluate the awareness and accessibility of the local primary care dermatology guideline. Key findings from the survey evaluation were shared with committee members.

Responders suggested that increased promotion of the guideline would be useful along with improved access via the SEL website. Responders noted additional resources that are used to support the management of dermatological conditions in primary which includes resources from NICE CKS, the British Association of Dermatologists and the Primary Care Dermatology Society. Following the outcome of the survey evaluation, the March 2025 update of the guideline included user friendly updates such as flowcharts, links to photos and an alphabetised index page. Additional next steps following the outcome of the survey evaluation, include the local adoption of national guidelines where possible.

Committee members noted the SEL primary care dermatology guidelines evaluation summary.

8. Updated Inflammatory Bowel Disease (IBD) outcomes and monitoring Framework 25/26

The SEL ICB Medicines Optimisation Lead for the IBD sub-group presented this item which has been updated and approved via the IBD sub-group. The IBD outcomes and monitoring framework includes the two new following audits:

- Review of sequential use of biologic therapies in Crohn's disease (CD) and ulcerative colitis with a focus on patients who have failed 4 or more advanced therapies with different mechanisms of action.
- Dual advanced therapy in CD (off-label)

Committee members approved by consensus the updated IBD outcomes and monitoring framework 2025/26.

9. Expanding the treatment options for the use of dual advanced therapy in Crohn's Disease

The applicants were in attendance to present this request on behalf of the IBD sub-group. This request is for a small cohort of patients, with complex CD where remission has not been achieved through biological monotherapy or combination therapy with immunomodulators, surgical interventions and inclusion within a clinic trial is inappropriate and there is a rationale for targeting two mechanisms of action to achieve remission.

Currently, there is local agreement for the use of dual advanced therapy consisting of infliximab or adalimumab plus vedolizumab or ustekinumab for patients with refractory CD who meet the strict criteria for use. The decision to initiate dual advanced therapy is discussed and agreed by a multidisciplinary team and evidence of disease progression despite optimised treatment is proven via imaging or endoscopy. With the availability of biosimilar ustekinumab, dual advanced therapy is more cost-effective than previously. Additionally, the availability of vedolizumab and infliximab as subcutaneous preparations enables patients to have access to dual biologic therapy at home.

The cohort of patients who may be eligible for treatment with the additional treatment options for dual advanced therapy in this setting would otherwise require an individual funding request (IFR) to access treatment. However, due to the lack of individuality and as this is an identified cohort of patients, the use of IFR requests in this setting would not be appropriate and a local commissioning decision will be recommended to support use.

In line with this, committee members were requested to consider the approval of the following additional treatment options for the use of dual advanced therapy in CD:

- Risankizumab plus adalimumab OR infliximab
- Ustekinumab and upadacitinib
- Ustekinumab and vedolizumab

The Formulary Pharmacist provided a brief overview of the evidence to support the additional treatment options for the use of dual advanced therapy in CD. There were no RCTs found investigating any of the new combinations proposed in this request and data were limited to observational studies.

A U.S. retrospective observational study of 10 Crohn's disease patients previously exposed to multiple biologics tested upadacitinib in combination with ustekinumab. Most achieved remission and joint pain improved in most patients with extra-intestinal symptoms. No patients required surgery, and the combination appeared effective and well tolerated, though based on a very small sample.

A systematic review of 30 studies (279 patients, 76% with Crohn's disease) found that combining biologics or advanced therapies achieved a clinical response in 59% and endoscopic remission in 34% of patients. The most common combinations were anti-TNFs with vedolizumab (48%) and ustekinumab with vedolizumab (19%). Adverse events occurred in 31% of patients, and serious adverse events in 6.5%. Due to small sample sizes and inconsistent reporting, the authors could not compare safety or effectiveness between combinations or recommend specific regimens, but no new safety concerns were identified.

From a cost perspective, the additional treatment options for the use of dual advanced therapy in this setting is within the financial threshold delegated to the committee. The highest potential costs are unlikely to be materialised as the most cost-effective combinations (e.g. ustekinumab and adalimumab) will be used according to the patient characteristics. Where more than one combination is suitable, the lowest cost option will be selected. Although this is an additional cost to the healthcare system, anticipated off-set costs include the prevention of complex surgical care, recurrent admissions to hospital and use of home parenteral nutrition. If approved, patient numbers and outcomes in this setting will be reported as part of the IBD outcomes and monitoring framework.

The associated criteria for use document for dual advanced therapy in CD has been updated in line with the updated proposal to reflect the expansion of drug combinations and note that cost effective combinations should be considered first line where clinically appropriate.

A query was raised in relation to any plans to publish the data collected locally for the use of dual advanced therapy in this setting to help contribute to the limited data which is currently available. The presenter clarified this would only be beneficial if carried out as a bigger aggregated cohort with other centres. It is anticipated that good efficacy and safety data will become available in the next few years as use increases.

A comment was raised regarding the combination of upadacitinib and vedolizumab where patients are inducted on upadacitinib until they are stable on vedolizumab and whether this approach is being considered via the IBD sub-group, given that IFRs for this regimen have previously been approved locally. The presenter confirmed the long-term use of dual advanced therapy was only considered by the IBD sub-group as opposed to use as induction therapy. Additionally, this particular combination was discussed by IBD sub-group and not supported for inclusion as the updated combinations proposed offer broader choice at a more reasonable cost impact, as the combinations include a biosimilar. Additionally, further treatments will be available in CD (mirikizumab and guselkumab) in the near future which may be options before dual advanced treatment. In view of this, the sub-group did not feel that the significant cost impact from this particular combination could be justified.

Committee members approved by consensus the additional treatment options for the use of dual advanced therapy in Crohn's Disease.

ACTION: IBD Pathway to be updated to reflect the new treatment options for the use of dual advanced therapy in Crohn's Disease

10. Standing items

- Formulary submissions tracker

Noted.

- NICE Technology Appraisal (TA) Guidance Summary – *ICS & NHSE attributed medicines*:

The summary was noted, and RAG categories were agreed by consensus, where it was possible to confirm the RAG status. For NICE TA 1074 - sparsentan for treating primary IgA nephropathy, the cost impact of implementing this NICE TA exceeds the financial threshold delegated to the committee and will require escalation to the Executive Committee for information.

ACTION: Estimated cost impact to be escalated to the Executive Committee for information

- For information and noting:

- Adult and paediatric formulary updates - noted by committee members

11. Formulary submission: Drospirenone (Slynd®) as a second-line progestogen only contraceptive pill

This formulary submission originates from a Consultant Obstetrician and Gynaecologist and requests the use of drospirenone (Slynd®) as a second-line progestogen only contraceptive pill after desogestrel. The application requests a Green RAG category for the use of drospirenone in this setting. The application is supported by the six local authorities in SEL, as commisisoners of sexual and reproductive health services.

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

Drospirenone is a potent progestogen, and spironolactone derivative with anti-mineralocorticoid and mild anti-androgenic activity and no estrogenic or glucocorticoid activity. It is a progestogen only pill

(POP) oral contraceptive licensed in women and adolescents of reproductive age after menarche. The dosing window is broader for drospirenone compared to other POP treatments, as contraceptive efficacy is reduced if a pill is taken more than 24 hours since the last dose, as opposed to 12 hours for desogestrel and 3 hours for traditional POPs. Another reported advantage of drospirenone over other POPs is that it has an improved bleeding profile. Due to the anti-mineralocorticoid effect of drospirenone, it is potassium sparing and therefore use in patients with severe renal insufficiency is contra-indicated. The product information recommends potassium is checked in the first treatment cycle in women with renal insufficiency and during concomitant use of potassium-sparing medicinal products.

NICE guidance recommends that women requiring contraception should be given information about and offered a choice of all methods including POPs. The current POPs on the formulary are levonorgestrel, norethisterone and desogestrel (third generation POP and the most common choice).

The evidence base for the use of drospirenone in this setting is primarily from two pivotal studies, an open label study and a systematic review which provided the licence for drospirenone in the UK and EU. The first trial was a single-arm study and the second trial was a double-blind, double-dummy design with an active comparator (desogestrel). In the two pivotal licensing studies, drospirenone was given to 1,571 women for one year up to 13 cycles; 8 pregnancies occurred and the pooled Pearl Index (PI - number of unintended pregnancies per 100-women years) was 0.73 (95%CI 0.31-1.43). Overall, all the 8 pregnancies with drospirenone over the 2 trials occurred in women under the age of 35 as “method failure” i.e. during perfect medication cycles.

In the second trial, there was a lower rate of overall bleeding and unscheduled bleeding (with drospirenone compared with desogestrel. However, in the first trial, 4.2% women withdrew from the study early with abnormal bleeding, while in the second study 3.3% and 6.6% of women taking drospirenone and desogestrel withdrew from the study respectively owing to abnormal bleeding

From a safety perspective there were no recorded venous thromboembolism (VTE) events in the pivotal studies, however the authors commented that the studies were not large enough to evaluate VTE events. Additionally, there were very few reports of hyperkalaemia in the studies. The most frequent treatment-related adverse effects were acne, headache, and abnormal uterine bleeding.

- **Applicant’s presentation**

The applicant and the Women’s Sexual Health Consultant were in attendance to present the submission and field any questions. The applicant’s declaration of interest was noted. The applicant summarised the application noting that the desired RAG category is Green and the place in therapy for drospirenone is a second line POP after desogestrel, particularly in women who experience unscheduled bleeding with desogestrel. The applicant reiterated the benefits of drospirenone and the benefits of its anti-mineralocorticoid and mild anti-androgenic activity, which introduce some theoretical benefits such as a potential to mitigate hormonal acne, hirsutism, and bloating symptoms. This is particularly helpful in the adolescent (under 16 years old) population which is prevalent locally due to the local paediatric gynaecology service which is also a tertiary centre. The applicant noted that although the cost of drospirenone is significantly higher in comparison to alternative POPs already on the formulary, the availability of drospirenone may provide offset costs from admissions associated with abortions or complex surgeries.

A comment was raised regarding any additional benefits to drospirenone in addition to the missed pill window and anti-mineralocorticoid effect. The applicant explained the 4-day hormone free pill interval which encourages a menstrual like scheduled bleed is beneficial to some patients. The applicant also noted there has been some concerns regarding the 4-day hormone free pill interval and the impact on ovulation, however drospirenone as a POP is at a higher dose of 4mg in comparison to the dose of drospirenone within combined oral contraceptive pills (3mg) and the long half-life of drospirenone at 4mg is unlikely to impact ovulation.

Clarification was requested regarding the lower risk of unscheduled bleeding with drospirenone and whether this is only in comparison to desogestrel or also in comparison to levonorgestrel and norethisterone. The applicant confirmed the majority of the studies for drospirenone used desogestrel as the comparator, in line with this the lower risk of unscheduled bleeding is primarily in comparison to desogestrel.

A query was raised regarding the place in therapy of levonorgestrel and norethisterone as a POP. The applicant clarified that the prescribing of levonorgestrel and norethisterone as a POP is generally based on the experience of the clinician and the clinical setting. Since the availability of desogestrel, levonorgestrel and norethisterone have become less favourable due to their short, missed pill window of 3 hours.

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

Committee members discussed the application and members acknowledged there is a patient cohort who could benefit from drospirenone as an alternative POP where desogestrel and other forms of contraception are not suitable.

Committee members approved by consensus the formulary inclusion of drospirenone as Green (initiation in primary or secondary care) as a second line progestogen only pill. Committee members also agreed by consensus that the formulary should include a note recommending the appropriate monitoring of potassium levels in women at increased risk of hyperkalaemia i.e. women concurrently prescribed potassium sparing medications.

ACTION: Formulary recommendation to be drafted and presented at a future meeting
ACTION: Drospirenone as a second line progestogen only pill to be added to the SEL adult JMF, including information regarding the appropriate monitoring of potassium levels in women at increased risk of hyperkalaemia

12. Any other business

This is the last meeting for the Lead Formulary Pharmacist. Committee members offered their thanks and appreciation to the Lead Formulary Pharmacist for their invaluable support and significant contributions to the Committee over the years and shared farewell messages.

IMOC dates for the next 3 months

Date	Time	Venue
Thursday 18th September 2025	2pm – 4:30pm	MS Teams
Thursday 16 October 2025	2pm – 4:30pm	MS Teams
Thursday 20th November 2025	2pm - 4.30pm	MS Teams