NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 16 April 2024 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Dr V Chieng	Ms L Cameron	
Ms A Davie	Dr D Culligan	
Ms F Doney (Vice-Chair)		
Dr L Elliot (Chair)		
Ms M Galvin		
Mrs G McKerron (until 8.2)		
Mrs E Milne		
Mrs S O'Beirne		
Mr M Paterson		
Dr K Simpson		
Mr R Sivewright (from item 4)		

IN ATTENDANCE
Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team.
Ms Cynthia Santiago, Associate Specialist/Retina, for item 4.
Mrs Christine Standen, Formulary and Medicines Management Pharmacist.

OBSERVER
Ms Claire Douglas, Primary Care Advanced Pharmacist/Team Co-ordinator, Aberdeen City Health & Social Care Partnership.

Note: some items were taken outwith agenda order.

ITEM	SUBJECT	ACTION
	WELCOME The Chair welcomed members, opened the meeting, and noted that a quorum was present. OBSERVER The Chair welcomed Ms Claire Douglas, Primary Care Advanced Pharmacist/Team Co-ordinator, Aberdeen City Health & Social Care Partnership, to the meeting as an observer.	
1.	**APOLOGIES** Apologies for absence were requested and noted.	
2.	**MINUTE AND DECISIONS**	
2.1.	**DRAFT MINUTE OF THE MEETING HELD 19 MARCH 2024** Members accepted the draft note of the meeting subject to minor typographical changes. The corrected final approved minute will be in the public domain within 21 days of final approval.	**FD**
2.2.	**FORMULARY GROUP DECISIONS MARCH 2024 - PUBLISHED 02/04/2024** Members ratified the decisions of the March 2024 meeting as published.	

4. PRESENTATION/DISCUSSION (AFLIBERCEPT 114.3MG/ML SOLUTION FOR INJECTION)

Ms. Santiago, Associate Specialist/Retina, attended the meeting to discuss the potential introduction of aflibercept 114.3mg/mL solution for injection in neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular oedema (DMO).

At the March meeting members queried if introducing the 8mg strength would negatively affect the opportunity to benefit from the availability of the 2mg biosimilar.

Ms. Santiago confirmed that following the experience with brolucizumab, the service first wants to establish that any new drug coming to market is safe.

Aflibercept 2mg is safe, and the new 8mg dose appears to be safe and has the provisional advantage of being more durable, so patients need to be treated less frequently. This has the additional benefit of lowering the risk of infection or inflammation in the eye, as each injection exposes the eye to the risk of infection or inflammation. However, it is four times the dose that the service is accustomed to giving in the eye, and it was only after several months of use of brolucizumab that adverse effects were noticed in the eye.

The volume of injection into the eye is higher for the 8mg injection, 0.7mL compared to 0.5mL for the 2mg dose. The 0.5mL injection does not increase the intraocular pressure (IOP) of the eye. If the 0.7mL injection increases IOP and the injection is given by ophthalmologists then it is less of an issue because ophthalmologists are trained to do paracentesis. However in the UK, much of the injection service is done by nurses and opticians and because of ethical issues these professions cannot be trained to do paracentesis. A protocol is in place should a person have an increase in IOP at clinics.

If the 8mg/0.7mL injection was available the service would have a careful introduction so as not to destabilise the current service if there are adverse events with the high-dose larger volume preparation.
The preference is to give the smallest dose possible and move to the larger dose only if the response is not as durable as the service would want it to be. Local audit for aflibercept 2mg showed ~20% of patients cannot extend treatment to 12 weeks or more.

Aflibercept 8mg is showing promise but would not be a preferred/first-line option, and more real-world data is required to support potential treatment strategies. There are data from the United States (US), but only for 6 months and the system is different in the US (only ophthalmologists administer intravitreal injections).
However, it is potentially a promising addition particularly for those patients that cannot extend their treatment interval beyond 8 weeks, and for those patients that find it difficult to travel and/or come regularly for appointments.
Patients are on different pathways and attend appointments because they know that the injections can ‘hold’ their sight.
Mindful that patients can relapse at any time, clinicians would be concerned if patients were not seen for more than 4 months. Face-to-face clinics are essentially for complex treatment-resistant patients or patients that have problems during the course of treatment.

Ms. Santiago confirmed that the service will know within the first few months how staff are coping with the 8mg injection. The service is trying to offer the best treatment for these vulnerable patients by giving drugs that give the best response but are safe and durable. The 8mg dose would be an additional treatment option initially for those that are not able to extend beyond 4-8 weeks with current therapies.

The Chair thanked Ms. Santiago for attending the meeting and clarifying the proposed use of aflibercept 8mg intravitreal injection.

Ms. Santiago left the meeting before decision-making.

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3.3 AFLIBERCEPT 114.3MG/ML SOLUTION FOR INJECTION

There were no declarations of interest recorded in relation to this product.

Members acknowledged that this new formulation of aflibercept is wanted for capacity reasons, and the increased treatment window will free up some capacity which will mean that ultimately more eyes can be treated which will also increase costs.
There is uncertainty that there will be an 8mg biosimilar available at the time of marketing of the 2mg biosimilar.

The Group supported the service's request and accepted the restricted local need for the higher dose 8mg aflibercept intravitreal injection for patients where the 2mg injection does not provide a durable response.

SBAR - Aflibercept 114.3mg/mL solution for intravitreal injection (Eylea®) is routinely available in line with local guidance.
Indication under review: for the treatment of adults with neovascular (wet) age-related macular degeneration (nAMD)
Restriction: as an alternative choice when aflibercept 2mg does not provide a durable response.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Eylea® must only be administered by a qualified healthcare professional experienced in intravitreal injections. **FTEAM**

SBAR - Aflibercept 114.3mg/mL solution for intravitreal injection (Eylea®) is routinely available in line with local guidance.
Indication under review: for the treatment of visual impairment due to diabetic macular oedema (DMO) in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline.
Restriction: as an alternative choice when aflibercept 2mg does not provide a durable response.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Eylea® must only be administered by a qualified healthcare professional experienced in intravitreal injections. **FTEAM**

3. MATTERS ARISING

3.1. Action LOG

The action log was noted.

Additional items not included on the agenda.

TRIAL - MEMBERS GIVEN MORE TIME TO REVIEW MEETING PAPERS

Mrs Standen confirmed that the trial period for issuing the meeting papers earlier has ended. She ran an in-meeting poll to ascertain if members supported continuing the change.

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The poll showed a resounding preference to continue issuing the meeting papers earlier.

The Formulary Team processes will be updated. **FTEAM**

RIVAROXABAN 2.5MG (IN COMBINATION WITH ASPIRIN) FOR THE PREVENTION OF ATHEROTHROMBOTIC EVENTS IN ADULTS WITH SYMPTOMATIC PERIPHERAL ARTERY DISEASE

At the September 2023 meeting the Group was minded to accept low-dose rivaroxaban (in combination with aspirin) for the prevention of atherothrombotic events in adults with symptomatic peripheral artery disease, restricted to use for those who underwent a successful revascularisation procedure (complex endovascular intervention, surgical bypass or hybrid intervention) treated for critical limb-threatening ischaemia or aneurysmal disease.
Members noted that the current DOAC guidance does not include this regimen and its prophylactic indication, but the requestor/service indicated that they would be glad to be involved in creating an addendum to the current guidance.
The Group requested that the addendum to the current DOAC guidance was accepted by the Medicine Guidelines and Policies Group (MGPG) to allow publication of the formulary decision.

Ms Doney confirmed that there have been emails exchanged, and the service is less inclined to support the production of guidance for Primary Care. It is now felt that an addendum to the current DOAC guidance for atrial fibrillation would be inappropriate. In addition, there are no guidelines for Primary Care for the treatment of pulmonary embolism or deep vein thrombosis on balance after discussion with haematology the feeling is that a guideline would not be necessary due to the prophylactic nature of the low dose rivaroxaban with aspirin regimen as per the Compass trial.

Members reiterated the request for a protocol/guidance to support prescribing (and monitoring in Primary Care). **FTEAM**
Additionally a member highlighted that the guidance would be useful for patient safety audits in practice. Practices often do audits of patients that are taking combination antiplatelet plus DOAC looking for an indication as to why patients are on both agents. From a patient safety perspective, if there is no guidance from the surgeons then practices might stop one or other of the agents because there is no clinical guideline to say why they are potentially breaching best practice.

3.2. *H.PYLORI* SECOND-LINE PENICILLIN ALLERGY TREATMENT REGIMEN (UPDATE)

At the February 2024 meeting, members queried the new treatment option [second-line penicillin allergy], especially in light of the strengthened Medicines and Healthcare products Regulatory Agency (MHRA) recommendation. Pending information from the service and Antimicrobial Management Team (AMT), members agreed to update the current *H.Pylori* guidance in line with the request but withhold publication of the new second-line penicillin allergy treatment regimen.

Ms Doney shared emails from Dr Phull and Dr Bateman (Chair of the AMT) confirming:
- that the treatment regimens are in line with the Medicines and Healthcare products Regulatory Agency (MHRA) guidance
- the antibiotic choices were discussed extensively during the development of the guidance and in cognisance of the extant MHRA guidance at the time which had already highlighted several safety concerns, and ensuring that these drugs were only used where clinical benefit would outweigh risk
- this is a treatment directed guideline rather than empiric for second-line treatment in penicillin allergic patients and the anticipated numbers are small
- Scottish Antimicrobial Prescribing Group (SAPG) provided a position statement for

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AMTs which contains the following statement - *Fluoroquinolones have an important position in many infection management guidelines in Scottish health boards as alternatives to beta lactams in true penicillin allergy. Fluoroquinolones are also frequently the only available oral agent for some resistant Gram-negative infections*

- SAPG supports AMTs in the use of fluoroquinolones as part of the broader local antimicrobial stewardship programme which includes timely intravenous (IV) to oral switch. It is reasonable for AMTs to consider fluoroquinolones in patients where the only alternative antibiotic therapy would be a broader spectrum alternative, or one delivered by the IV route.

The Group supported publication of the *H.Pylori* second-line penicillin allergy regimen. **FTEAM**

Members also requested addition of a comment on the formulary confirming that the regimens published have taken into account the strengthened MHRA guidance, as prescribers may be looking at the regimens and wondering if this had been considered. **FTEAM**

5. NEW PRODUCT REQUESTS

5.1. SMC 2609 - LONCASTUXIMAB TESIRINE (DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL) AND HIGH-GRADE B-CELL LYMPHOMA (HGBL))

There were no declarations of interest recorded in relation to this product.

The Group considered the request for loncastuximab as monotherapy for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy where chimeric antigen receptor (CAR) T-cell therapy is unsuitable, not tolerated or ineffective.

The Group noted that:

- loncastuximab:
  - [for this indication] meets SMC end of life and orphan equivalent criteria, and was accepted for use in NHS Scotland following a full submission assessed under the end of life and orphan equivalent medicine process, the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
  - is given at a dose of 0.15mg/kg every 21 days for 2 cycles, followed by 0.075mg/kg every 21 days for subsequent cycles until disease progression or unacceptable toxicity.
  - is administered intravenously over 30 minutes, and unless contraindicated, dexamethasone 4mg is administered orally or intravenously beginning the day before administering loncastuximab to mitigate pyrrolobenzodiazepine (PBD)-related toxicities
  - has a Conditional Marketing Authorisation from the MHRA
- evidence comes from the LOTIS-2 trial:
  - the Primary outcome was the objective response rate (defined as the proportion of patients with complete response (CR) or partial response (PR)) was 48% (CR 25% and PR 23%)
  - the Secondary outcomes were median progression free survival (4.9 months) and median overall survival (9.5 months)
  - the median duration of treatment was 45 days and the median number of treatment cycles was 3, however this ranged from 1 to 26 cycles
- LOTIS-2 trial was an open-label, single arm study so lacked a direct comparator, and only included patients with an ECOG performance score of 0 to 2
- patient numbers will be relatively small
- minimal cost-offset is expected
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of loncastuximab

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The Group accepted the restricted local need for loncastuximab as monotherapy for the treatment of adults with relapsed or refractory DLBCL and HGBL, after two or more lines of systemic therapy where CAR T-cell therapy is unsuitable, not tolerated or ineffective, as outlined in SMC 2609.

SMC 2609 - Loncastuximab tesirine 10mg powder for concentrate for solution for infusion (Zynlonta®) is routinely available in line with national guidance (SMC 2609).
Indication under review: as monotherapy for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy where chimeric antigen receptor (CAR) T-cell therapy is unsuitable, not tolerated or ineffective.
In an open-label, single-arm, phase II study, in adults with relapsed or refractory DLBCL (which included HGBL) following two or more multi-agent systemic treatment regimens, Loncastuximab tesirine was associated with an overall response rate of 48%.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Locastuximab must only be administered under the supervision of a healthcare professional experienced in the diagnosis and treatment of cancer patients. FTEAM

5.2. SMC 2486 - FINERENONE (CHRONIC KIDNEY DISEASE (STAGE 3 AND 4 WITH ALBUMINURIA))

There were no declarations of interest recorded in relation to this product.

The Group considered the request for finerenone for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.

The Group noted that:

- the recommended target dose is 20mg finerenone once-daily orally but dose adjustments may be required based on estimated glomerular filtration rate (eGFR) and potassium levels
- serum potassium and eGFR should be measured at baseline and re-measured 4 weeks after initiation, or restart of treatment or increase in dose. Thereafter, serum potassium should be re-measured periodically and as needed based on patient characteristics and serum potassium levels.
- the service propose that finerenone will be prescribed in Primary Care on the recommendation of renal specialists
- evidence comes from FIDELIO-DKD which compared finerenone with placebo in adults with chronic kidney disease and type 2 diabetes
- after a median of 2.6years, the composite renal primary outcome (first occurrence of kidney failure, a sustained decline in eGFR of ≥40% compared to baseline or death from renal causes) had occurred in significantly ($p<0.001$) fewer finerenone patients compared to placebo (18% versus 21% respectively)
- National Institute for Health and Care Excellence (NICE) has accepted finerenone [for this indication] only if it is add-on to optimised standard care; this should include the highest tolerated licensed doses of angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs) and sodium-glucose cotransporter-2 (SGLT2) inhibitors
- in FIDELIO-DKD, only 4.6% of patients were receiving SGLT2 inhibitor therapy
- patient numbers are expected to be moderate and may increase with time

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- the service stated that finerenone will be used instead of spironolactone or eplerenone, as it is better in terms of side effects and effectiveness, and minimal off-set will be available from replacing these medicines

Members queried:
- what data there was to support the statement that finerenone is better than spironolactone and eplerenone in terms of side effects and effectiveness?
- would finerenone only be prescribed by the renal service, or would it also be prescribed by the diabetic service?
- what patient information is available for finerenone, and should it be included in the Sick Day Rule Cards?
- are all eligible patients currently attending clinics, or are some currently managed in Primary Care?
- should finerenone only be considered as add-on to optimised standard care (ACE inhibitors or ARBs and SGLT2 inhibitors)?

Members had a lengthy discussion about this medicine and felt that it would be beneficial to have a treatment protocol as the potassium level plays an important role in the management of this medicine.

Members requested more information and deferred decision-making to a future meeting. **FTEAM**

Decision deferred to a future meeting.

5.3. SMC 2518 - OLAPARIB (HER2-NEGATIVE, HIGH RISK EARLY BREAST CANCER)

Mr Paterson declared a personal, non-specific interest in relation to AstraZeneca UK Limited, and took part in decision-making.

The Group considered the request for olaparib as monotherapy or in combination with endocrine therapy for the adjuvant treatment of adults with germline BRCA1/2-mutations who have human epidermal growth factor receptor 2 (HER2)-negative, high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy.

The Group noted that:
- the recommended dose is 300mg taken twice daily orally as monotherapy or in combination with endocrine therapy for up to one year, or until disease recurrence, or unacceptable toxicity
- olaparib is included in the Scottish Cancer Clinical Management Pathways for Early Breast Cancer for this indication
- before olaparib treatment is initiated for adjuvant treatment of HER2 negative high-risk early breast cancer, patients must have confirmation of deleterious or suspected deleterious BRCA1/2[*] mutation using a validated test
- evidence comes from OlympiA (olaparib versus placebo):
  - Primary outcome – the number of invasive disease-free survival events (defined as the time from randomisation until first invasive disease occurrence or death from any cause) was 106 for olaparib and 178 for placebo
  - Secondary outcome – Overall survival (number of deaths) were 75 for olaparib and 109 for placebo
- the service stated that olaparib will replace capecitabine in triple negative breast cancer and abemaciclib in hormone receptor positive/HER2 negative group. Minimal cost off-set is available for capecitabine as it is available generically.
- there is no direct or indirect evidence comparing olaparib with capecitabine or abemaciclib
- patient numbers are expected to be very small

[*] BRCA1 (BReast CAncer gene 1) and BRCA2 (BReast CAncer gene 2)

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- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of olaparib

The Group accepted the restricted local need for olaparib as monotherapy or in combination with endocrine therapy for the adjuvant treatment of adults with germline BRCA1/2-mutations who have HER2-negative, high-risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy, as outlined in SMC 2518.

SMC 2518 - Olaparib 100mg, 150mg film-coated tablets (Lynparza®) is routinely available in line with national guidance (SMC 2518).
Indication under review: as monotherapy or in combination with endocrine therapy for the adjuvant treatment of adults with germline BRCA1/2-mutations who have human epidermal growth factor receptor 2 (HER2)-negative, high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy.
In a phase III study, adjuvant olaparib after the completion of neoadjuvant or adjuvant chemotherapy, significantly improved invasive disease-free survival compared with placebo in patients with high-risk, HER2-negative early breast cancer with a germline BRCA1/2-mutation.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment with olaparib should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. FTEAM

5.4. SMC 2578 - AVACOPAN (SEVERE ACTIVE GRANULOMATOSIS WITH POLYANGIITIS OR MICROSCOPIC POLYANGIITIS)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for avacopan in combination with a rituximab or cyclophosphamide regimen, for the treatment of adults with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).

The Group noted that:

- the recommended dose is 30mg taken orally twice daily. Avacopan should be administered in combination with rituximab or cyclophosphamide regimen and glucocorticoids as clinically indicated.
- liver function tests and full blood count must be obtained prior to initiation and then monitored as clinically indicated
- the service plans to stop avacopan after 12 months or earlier if patients have an allergic or adverse reaction or the requirement to restart steroids beyond short-term (<6 weeks, rescue steroids plan)
- evidence comes from ADVOCATE, a phase III randomised, double-blind, double-dummy, active-controlled study, limited to 12-months:
  - Primary outcomes (avacopan group vs prednisolone group (steroid-reduction))
    - clinical remission at week 26 was 72% vs 70%
    - sustained remission at week 52 was 66% vs 55%
  - Secondary outcomes (avacopan group vs prednisolone group)
    - mean cumulative steroid dose was 1,675.5mg vs 3,846.9mg
    - proportion of patients using glucocorticoids beyond week 26 was 27% vs 39%
- patient number are expected to be small
- the service will initially supply avacopan from the managed service but supply via homecare will ultimately be the best approach

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- the service states that the key advantages of avacopan is steroid minimisation and early withdrawal, achieving higher rates of remission and better kidney function at 1 year of treatment
- minimal drug cost offset will be available as prednisolone is available generically. However, indirect savings from a reduction of steroid related toxicity may be seen.
- the vasculitis clinic that most patients will be treated by is multidisciplinary team based with renal and rheumatology integrated disciplines
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of avacopan

The Group accepted the restricted local need for avacopan in combination with a rituximab or cyclophosphamide regimen, for the treatment of adults with severe, active GPA or MPA.

SMC 2578 - Avacopan 10mg capsules (Tavneos®) is routinely available in line with national guidance (SMC 2578).
Indication under review: in combination with a rituximab or cyclophosphamide regimen, for the treatment of adults with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).
In a phase III study, avacopan demonstrated non-inferiority to prednisone for remission at week 26, and was superior to prednisone for sustained remission at week 52 in patients with GPA or MPA.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and monitored by healthcare professionals experienced in the diagnosis and treatment of GPA or MPA. **FTEAM**

6. FORMULARY REVIEW

6.1. FORMULARY UPDATES

There were no declarations of interest recorded in relation to these products.

Ms Doney confirmed that:

- Ovestin® 1mg cream has been discontinued and is now available as a generic medicine, estriol 1mg/g vaginal cream. Both products have the same Marketing Authorisation Holder (MAH) and the NHS list price has increased - Ovestin® was £4.45/15g pack and estriol 1mg/g vaginal cream is £5.45/15g.
- generics are now available for micronised progesterone 100mg capsules, licensing is in line with Utrogestan® 100mg oral capsules. The generics are available at a lower cost per pack [£4.62 and £6.27 compared to £6.60].
- the patent for rivaroxaban expires April 2024 however due to ongoing legal challenges this may extend the patent protection to 2026 for all but the 2.5mg tablets. The MHRA has licensed multiple generics as tablets and a new formulation of hard capsules.

Members supported updating the formulary entries to remove the brand names, and use ScriptSwitch to highlight generic switches were appropriate. **FTEAM**

The Formulary Team will notify colleagues in the Medicine Management Team of the increased cost for estriol 1mg/g cream, and potential for rivaroxaban to be included on the Scottish Drug Tariff. **FTEAM**

Ms Doney confirmed that:

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- the MAH confirmed that pralsetinib 100mg hard capsules (Gavreto®) has been discontinued, this is not for efficacy, safety or quality reasons, stock will remain available to purchase until 31st August 2024
- the MAH confirmed that Levemir® InnoLet® and Insulatard® InnoLet® 100units/mL solution for injection 3mL pre-filled pens are being discontinued and remaining stock is expected to last until at least the end of May 2024
- the discontinuations are considered low impact, as pralsetinib is currently non-formulary and other formulations/presentations of the insulins are available

FTEAM

Members supported updating the formulary noting the withdrawals/discontinuations.

6.2. PREFERRED BRANDS/PRODUCTS WITHIN THE MANAGED SERVICE

There were no declarations of interest recorded in relation to these products.

Mrs Standen reported that:

- a new contract for adalimumab and tocilizumab came into effect from 1 March 2024 and the new contract will enable some cost efficiencies for these medicines
- adalimumab
  - the current biosimilar of choice for adalimumab is Amgevita®. This has been the preferred adalimumab biosimilar since 2018 when Humira® (adalimumab originator) came off patent.
  - adalimumab is used by multiple specialities, including Rheumatology, Gastroenterology, Dermatology and Ophthalmology
  - a new biosimilar Yuflyma® has come to market, and is available as 40mg/0.4mL and 80mg/0.8mL, and it is citrate-free
  - the proposal is to:
    - keep current Amgevita® patients on Amgevita®
    - change the preferred biosimilar for new start adalimumab patients to Yuflyma®
    - revisit patients on Humira® and offer a switch to Yuflyma®
    - keep Amgevita® as the preferred biosimilar for paediatric patients requiring adalimumab 20mg/0.4mL solution for injection
- tocilizumab:
  - the new contract for tocilizumab includes the originator RoActemra® and the first biosimilar Tyenne®
  - tocilizumab is licensed for use in rheumatoid arthritis, juvenile idiopathic polyarthritis, giant cell arteritis and COVID-19
  - RoActemra® and Tyenne® are both available as 20mg/mL concentrate for solution for infusion for intravenous administration, and 162mg solution for injection in pre-filled pen/syringe for subcutaneous administration
  - the proposal is to:
    - switch current patients on RoActemra® to the new biosimilar Tyenne®
    - start new tocilizumab patients on Tyenne®
    - note the preferred biosimilar for tocilizumab to Tyenne®

The Group accepted the restricted local need for Yuflyma® and Tyenne®, as the preferred biosimilar medicines for adalimumab and tocilizumab respectively without the need for full submissions. These treatments are accepted as treatment options within treatment pathways for appropriate patients as identified by treating clinicians and subject to compliance with a biosimilar medicines prescribing framework.

Adalimumab 40mg/0.4mL, 80mg/0.8mL solution for injection in pre-filled pen/syringe (Yuflyma®) is routinely available in line with local guidance.
Indication under review: in line with the current formulary approval for adalimumab.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Yuflyma® treatment should be initiated

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	and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Yuflyma® is indicated. Ophthalmologists are advised to consult with an appropriate specialist before initiation of treatment with Yuflyma® (see SmPC section 4.4). Patients treated with Yuflyma® should be given the Patient Reminder Card.	**FTEAM**
	Tocilizumab 162 mg solution for injection in pre-filled pen/syringe, 20mg/mL concentrate for solution for infusion (Tyenne®) is routinely available in line with local guidance. **Indication under review: in line with the current SMC and Healthcare Improvement Scotland advice for the reference tocilizumab product [RoActemra®].** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of conditions for which Tyenne® is indicated** **All patients treated with Tyenne® should be given the Patient Alert Card.**	**FTEAM**
	Biological medicines, including biosimilar medicines, should be prescribed by both generic and brand name and the trade name and batch number should be recorded on the patient's prescription, case record or other appropriate clinical system.	
	6.3. ADHD MEDICATION REVIEW There were no declarations of interest recorded in relation to these products. Ms Doney summarised the differences between the NICE guideline [NG87] for the diagnosis and management of attention deficit hyperactivity disorder (ADHD) and the current local prescribing guidance. SIGN 112 was withdrawn several years ago making NG87 the relevant extant national guideline for review. The Group did not support: • extending the lower age range to include children aged 5 to under 6 years. Members were not comfortable extending the formulary acceptance to this age group as this would be off-label prescribing for all of the ADHD medicines. Specialists could hand-over prescribing when the child was aged 6 years. • extending the upper age range to include adults (18 years and older). Members were not comfortable extending the formulary acceptance until there was a more established service for ADHD monitoring and treatment is available with the appropriate support from the specialist service. Mindful of the ongoing supply issues for ADHD medicines, the Group supported the following changes to the formulary and local guidance for the pharmacological management of ADHD for children and adolescents (6 to < 18 years): • include modified-release methylphenidate as an additional first-line choice (with immediate-release methylphenidate) • lisdexamfetamine becomes the sole second-line choice, and the entry changed to generic in preparation for the loss of patent • dexamfetamine becomes an option for those whose ADHD symptoms are responding to lisdexamfetamine but who cannot tolerate the longer effect profile • atomoxetine and guanfacine move to third-line for those who cannot tolerate methylphenidate or lisdexamfetamine or if their symptoms have not responded to separate 6-week trials of lisdexamfetamine and methylphenidate, having considered alternative preparations and adequate doses • remove mention of tricyclic antidepressants/imipramine and melatonin from the local guidance Members discussed the potential reclassification of clonidine to allow prescribing in	**FTEAM**

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Primary Care. However, members requested more information (an SBAR) to support decision-making. Clarity is required on when off-label clonidine would be used (pathway, patient characteristics) and an indication of the volume of patients currently receiving clonidine for ADHD. **MHOMMG**

7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED APRIL 2024

The Group noted the SMC advice published April 2024.

The following SMC accepted medicines have not been processed within a 60-day timescale:

- SMC 2611 daridorexant (Quviviq®)▼ (submission expected)
- SMC 2635 dostarlimab (Jemperli®)▼
- SMC 2618 mavacamten (Camzyos®)▼ (submission expected)
- SMC 2650 mirikizumab (Omvoh®)▼ (submission expected)
- SMC 2610 ritlecitinib (Litfulo®)▼
- SMC 2633 tirzepatide (Mounjaro®)

Local advice for these medicines and indications will be included in the April 2024 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

SMC 2652 BEVESPI® AEROSPHERE® (GLYCOPYRRONIUM/FORMOTEROL FUMARATE)

Mr Paterson declared a personal, non-specific interest in relation to AstraZeneca UK Limited, and took part in decision-making.

Ms Doney reported that previously due to the priming requirement of the Aerosphere® device the Respiratory Managed Clinical Network (MCN) has not supported formulary inclusion for other pharmacological agents in the Aerosphere® device.

The Group supported the previous position noting Bevespi® Aerosphere® as non-formulary as there is a local preference for alternative medicines.

SMC 2652 - Bevespi® Aerosphere® 7.2micrograms/5micrograms pressurised inhalation, suspension (glycopyrronium/formoterol fumarate) is not routinely available as there is a local preference for alternative medicines.
Indication under review: as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).
Glycopyrronium/formoterol fumarate (Bevespi Aerosphere®) offers an additional treatment choice in the therapeutic class of a long-acting muscarinic antagonist (LAMA) in combination with a long-acting beta2-adrenergic agonist (LABA).
Not routinely available as there is a local preference for alternative medicines. **FTEAM**

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED APRIL 2024

The Group noted the SMC provisional advice issued April 2024.

8.2. NATIONAL CANCER MEDICINES ADVISORY GROUP

The NCMAG Council meeting planned for March was postponed, no advice has been issued.

ITEM	SUBJECT	ACTION

Health Boards were advised '*As you may have been anticipating advice to be issued from NCMAG from our March Council meeting we would like to advise that the meeting to discuss proposals for breast cancer chemoprevention medicines was postponed. This postponement was at the request of our programme sponsor, Scottish Government*'.

An update will be provided when further information is available.

Additional item not included on the agenda.

8.3. NICE [ID6261] - REMDESIVIR AND TIXAGEVIMAB PLUS CILGAVIMAB FOR TREATING COVID-19

On 08 April National Institute for Health and Care Excellence (NICE) published final draft guidance for remdesivir and for tixagevimab-cilgavimab.
The final draft guidance recommends remdesivir as an option for treating COVID-19 in hospitals in specific patient groups, and tixagevimab-cilgavimab (Evusheld®) is not recommended for treating COVID-19 in adults who do not need supplemental oxygen and who have an increased risk of progression to severe COVID-19.

The final draft guidance is out for an appeal period (ends on 23 April 2024) and, assuming no appeals, the final guidance is expected to be published by NICE on 8 May 2024.

Information has been shared with the AMT, feedback is awaited.

9. OTHER BUSINESS

None.

10. DOCUMENTS FOR INFORMATION

Items 10.1 (Drug Safety Update March 2024), 10.2 (MedWatch March 2024), 10.3 (Antimicrobial Management Team minute January 2024) 10.4 (Primary Care Prescribing Group meeting minute January 2024), 10.5 (Medicine Guidelines and Policies Group (MGPG) meeting minute January 2024), 10.6, 10.7 and 10.8 (Grampian Area Drug and Therapeutics Committee (GADTC) meeting minute September 2023, November 2023 and January 2024) were noted.

11. AOCB

EPIMAX®

There were no declarations of interest recorded in relation to Aspire Pharma.

Ms Doney confirmed that there has been another report of corneal ulceration locally. Members supported removal of the preparations listed in the Field Safety Notice, Epimax® Original Cream, Epimax® Paraffin Free Ointment and Epimax® Ointment, from the formulary with information shared with colleagues so that an action plan can be developed by the Primary Care Prescribing Group. **FTEAM**

THANK YOU

The Chair confirmed this will be Mrs Standen's last meeting for a while and thanked her for her contributions to the Formulary Group.

ITEM	SUBJECT	ACTION

DATE OF NEXT MEETING

Tuesday 21 May 2024 starting at 14.30 via Microsoft Teams

Dr Louise Elliot

CHAIR'S SIGNATURE **Signature on file** **DATE 21 MAY 2024**