PROTECTIVE MARKING: NONE

NHS GRAMPIAN Minute of Formulary Group Meeting Tuesday 18 March 2025 at 14:30 via Microsoft Teams

PRESENT APOLOGIES APPROVED

Dr V Chieng Ms L Cameron
Ms F Doney Dr D Culligan
Mrs E Milne Ms A Davie

Dr L Elliot (Chair) Mrs M Galvin (and deputy Mrs S Howlett)

Mrs G McKerron Mr R Sivewright

Mrs S O'Beirne Mr M Paterson Dr K Simpson

IN ATTENDANCE

Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team.

ITEM SUBJECT ACTION

WELCOME

The Chair welcomed members, opened the meeting, and confirmed that a quorum was present.

1. APOLOGIES

Apologies for absence were requested and noted.

2. MINUTE AND DECISIONS

2.1. DRAFT MINUTE OF THE MEETING HELD 18 FEBRUARY 2025

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 FEBRUARY 2025 - PUBLISHED 03/03/2025

Members ratified the decisions of the February 2025 meeting as published.

3. MATTERS ARISING

3.1. Action Log

The Action log was not available for the meeting.

3.2. BUPRENORPHINE

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

January 2025 the Group discussed an SBAR requesting changes to the current formulary choices for opioid substitution. Members deferred decision-making and requested additional information regarding comparative costings, the local breakdown of methadone versus buprenorphine formulations, and if a product switch was being considered how it would be implemented including what support was planned for prescribers [in Primary Care].

The Group considered the additional information supplied by the specialist service noting that a switch from Suboxone® and Espranor® [to generic buprenorphine] was planned but information, in terms of a prescriber guide and patient leaflet, were not provided for the meeting.

Members considered the SBAR could be split into two parts. The first related to the changes to the formulary and the second relating to the logistics of changing existing stable patients from one product to another.

FORMULARY CHANGES

The Group was minded to support the changes to the formulary but requested a draft of the proposed revised formulary layout for sign-off by members.

FTEAM/ JC

SUBOXONE®/ESPRANOR® SWITCH

Primary Care colleagues reported that a ScriptSwitch message had already been deployed for Suboxone® without supporting information to assist prescribers with the change.

Primary Care colleagues queried if the potential workload switching patients from Suboxone® to generic buprenorphine would be picked up by the Substance and Medicines Use service and/or had been discussed with the local GMC/LMC?

Members noted that:

- switching existing stable patients may require titration of the alternative drug and additional monitoring
- the switch was planned for a vulnerable group of patients, and some patients will feel anxious about the change
- in some practices pharmacotherapy teams may be issuing Controlled Drug prescriptions and so involved in the switch
- prescribers in Primary Care will require support, and information need to be provided in a timely manner

The Group considered that the current messaging was potentially disjointed, with a ScriptSwitch message already deployed, and concerns that switch requests will be coming through quite rapidly to prescribers [independent prescribers not just General Practitioners] who have no information to support the change.

Ms Doney will provide feedback to the Service/Medicines Management Team.

FD

4. Presentation/discussion

None.

5. NEW PRODUCT REQUESTS

5.1. SMC 2618 - MAVACAMTEN (SYMPTOMATIC (NEW YORK HEART ASSOCIATION, NYHA, CLASS II TO III) OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY (OHCM))

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

The Group considered the request for mavacamten hard capsules for the treatment of symptomatic (New York Heart Association, NYHA, class II to III) obstructive hypertrophic cardiomyopathy (oHCM) in adults.

The Group noted that:

- HCM is the most common genetic disease affecting the heart muscle
- obstructive HCM (oHCM) represents approximately 66% of HCM cases, is also characterised by the presence of left ventricular outflow tract obstruction (LVOTO)
- patients with oHCM experience a progressive decline in their cardiac function and are at greater risk of developing heart failure, arrhythmias, and have a greater mortality risk
- management of the disease is currently pharmacological treatments to improve functional capacity and improve symptoms (beta-blockers, non-dihydropyridine calcium channel blockers and/or disopyramide) or surgical procedures

- mavacamten:
 - is the first medicine to be licensed for the treatment of oHCM
 - meets SMC orphan equivalent criteria for this indication and was accepted for use in NHS Scotland following a full submission
 - is taken at a recommended dose of 2.5mg to 15mg orally once daily. The dose is dependent on a patient's cytochrome P450 (CYP) 2C19 (CYP2C19) metaboliser phenotype and response to treatment. Before treatment initiation, patients' left ventricular ejection fraction (LVEF) should be assessed by echocardiography. If LVEF is <55%, mayacamten treatment should not be initiated.
- the effectiveness of mavacamten was compared with placebo in two main studies, EXPLORER-HCM and VALOR-HCM:
 - EXPLORER-HCM (n=251) the primary outcome was a composite functional outcome, designed specifically for the study. After 30 weeks of treatment, 37% of patients treated with mavacamten achieved the composite primary outcome compared with 17% of those treated with placebo. Additionally, 20% of patients in the mavacamten group achieved the more stringent combination of the composite primary outcome (patients achieving both improvement of ≥3.0 mL/kg/min increase in pVO2 and an improvement of ≥1 NYHA class), compared with 8% of patients in the placebo group.
 - Longer-term data is available from the extension study EXPLORER-LTE (n=231). Interim analysis (data cut-off August 2021), where 15% of patients had reached week 96 of mavacamten treatment, showed that patients receiving mavacamten continued to experience therapeutic benefits that were generally consistent with that in EXPLORER-HCM with regards to LVOT gradients, NYHA class, and other cardiac parameters.
 - VALOR-HCM (n = 112) studied patients with oHCM who were eligible for septal reduction therapy (SRT). The primary outcome was a composite of the decision to proceed with SRT prior to or at week 16, or remaining guideline eligible for SRT at week 16. After 16 weeks of treatment with mavacamten, 18% (10/56) of patients proceeded with SRT or were still eligible for SRT compared with 77% (43/56) of those who received placebo.
- the local estimate of patient numbers is higher than the estimate provided by the MAH to the SMC, and numbers will be cumulative as treatment may be taken for years
- this will be a new cost to the system, with the potential for a small cost offset if other treatments are discontinued
- the SMC advice takes account of the benefits of a PAS that improves the costeffectiveness of mavacamten
- · mavacamten is not available for prescribing in Primary Care
- the service confirmed that:
 - CYP2C1 testing is available locally via a manufacturer funded service
 - the additional echocardiograms required is manageable within current capacity
 - local practice/patient pathway will be based on the Liverpool pathway
 - a letter highlighting the risks associated with mavacamten will be issued to colleagues in Primary Care
- the potential for adverse events due to overexposure to mavacamten resulting from interaction with CYP2C19 inhibitors in ultra-rapid and intermediate CYP2C19 metabolisers and moderate or strong CYP3A4 inhibitors in poor and normal CYP2C19 metabolisers
- the need for ongoing supervision regarding pregnancy prevention

Members considered the supporting information issued on email before the meeting.

A member questioned if there were governance and ethical issues if a patient's CYP2C19 phenotype status was known and not shared.

Members queried if the CYP2C19 phenotype status data was owned by the NHS, rather than the company sponsoring testing, and if the results were open to be shared with other

services, and could be coded on a patient's record.

FTEAM

Members supported the letter for Primary Care but questioned if:

- the clinical indication oHCM should be coded and made Priority 1 on a patient's summary [so it will appear on the Emergency Care Summary], and also include a comment under the clinical coding, e.g., 'on mavacamten'?
- barrier contraception provided sufficient contraceptive cover to allow patients' to start mavacamten, and if this should be changed to barrier in addition to other contraceptive methods?
- there was a pathway to ensure patients have adequate contraceptive cover when taking mavacamten, e.g., will cardiology liaise with the sexual health service or Primary Care?

FTEAM

Members acknowledged that mavacamten, as the first pharmacological treatment licensed to treat oHCM, provided the opportunity for symptomatic control, improvements in quality of life, and potentially avoid or reduce the need for invasive cardiac surgery in those who do not respond to current standard of care for oHCM.

The Group accepted the restricted local need for mavacamten for the treatment of symptomatic NYHA class II to III oHCM in adults. In line with the submission members supported restricting mavacamten to use as an add-on to individually optimised standard care, unless these are contraindicated, ineffective or poorly tolerated.

SMC 2618 - Mavacamten (Camzyos®)▼ 2.5mg, 5mg, 10mg, 15mg hard capsules is routinely available in line with national guidance (SMC 2618).

Indication under review: for the treatment of symptomatic (New York Heart Association, NYHA, class II to III) obstructive hypertrophic cardiomyopathy (oHCM) in adults.

Restriction: as add-on to individually optimised standard care (with beta-blockers, non-dihydropyridine calcium channel blockers or disopyramide), unless these are contraindicated, ineffective or poorly tolerated.

In a double-blind, randomised, phase III study, the proportion of patients who achieved the composite primary outcome (that assessed exercise capacity and NYHA class) was significantly greater in the mavacamten group compared with placebo.

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 under the supervision of a physician experienced in the management of patients with cardiomyopathy.

Before treatment initiation, patients' left ventricular ejection fraction (LVEF) should be assessed by echocardiography (see SmPC section 4.4). If LVEF is < 55%, treatment should not be initiated.

Before initiation of treatment, women of childbearing potential must have a negative pregnancy test (see SmPC sections 4.4 and 4.6).

Patients should be genotyped for Cytochrome P450 (CYP) 2C19 (CYP2C19) in order to determine appropriate mavacamten dose.

FTEAM

5.2. SMC 2585 - TAFAMIDIS (WILD-TYPE AND HEREDITARY TRANSTHYRETIN AMYLOIDOSIS IN ADULTS WITH CARDIOMYOPATHY (ATTR-CM))

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

The Group considered the request for tafamidis 61mg hard capsules (Vyndaqel®) for the treatment of wild-type and hereditary transthyretin amyloidosis with cardiomyopathy (ATTR-CM).

The Group noted that:

- in patients with transthyretin amyloidosis, a blood protein called transthyretin is defective and breaks easily. The broken protein forms a fibrous substance, amyloid, that is deposited in tissues and organs around the body, including around nerves, where it interferes with their normal functions.
- ATTR-CM is a type of ATTR in which most deposits accumulate in the heart
- ATTR-CM is a progressive condition that can lead to heart failure, and treatment options are limited to managing symptoms and best supportive care
- tafamidis as Vyndagel[®]:
 - is the first medicine licensed for ATTR-CM
 - is a selective stabiliser of transthyretin. It attaches to transthyretin at the thyroxine binding sites, this prevents the protein from breaking up, thereby stopping the formation of amyloid and slowing down the progression of the nerve disease.
 - [for this indication] was accepted for use in NHS Scotland following a second resubmission assessed under the end of life and orphan medicine processes
 - [for this indication] was accepted for use only in the context of the SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios and the output from the PACE process
- evidence comes from ATTR-ACT, a multicentre, randomised, double-blind, phase III study:
 - the primary outcome was a hierarchical combination of 'all-cause mortality' and the frequency of cardiovascular (CV)-related hospitalisations during the study. All-cause mortality was a composite of all-cause mortality, heart transplantation or the implantation of a cardiac mechanical assist device.
- tafamidis meglumine (pooled dose groups) reduced the risk of all-cause mortality and CV-related hospitalisation compared with placebo over the 30-month study period. There were also significantly less declines in six minute walking test and Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score in tafamidis meglumine treated patients compared with placebo-treated patients
- patient numbers will be small, but will increase annually as treatment will potentially be taken for several years
- · the Service plans to use a homecare arrangement to supply tafamidis
- the SMC advice takes account of the benefits of a PAS that improves the costeffectiveness of tafamidis
- tafamidis is not available for prescribing in Primary Care

The Group request answers to the questions posed in the review, and accepted the restricted local need for tafamidis for the treatment of adults with wild-type and hereditary ATTR-CM.

SMC 2585 – Tafamidis 61mg soft capsules (Vyndaqel®)▼ is routinely available in line with national guidance (SMC 2585).

Indication under review: for the treatment of wild-type and hereditary transthyretin amyloidosis in adults with cardiomyopathy (ATTR-CM).

In a phase III study, 30 months of treatment with tafamidis (as meglumine) significantly reduced the risk of all-cause mortality and cardiovascular-related hospitalisation compared with placebo, in patients with wild-type or hereditary ATTR-CM.

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 should be initiated under the supervision of a physician knowledgeable

in the management of patients with amyloidosis or cardiomyopathy. When there is a suspicion in patients presenting with specific medical history or signs of heart failure or cardiomyopathy, etiologic diagnosis must be done by a physician knowledgeable in the management of amyloidosis or cardiomyopathy to confirm ATTR-CM and exclude AL amyloidosis before starting tafamidis, using appropriate assessment tools such as: bone scintigraphy and blood/urine assessment, and/or histological assessment by biopsy, and transthyretin (TTR) genotyping to characterise as wild-type or hereditary.

FTEAM

5.3. FG1 466/24 - VEDOLIZUMAB ((OFF-LABEL USE) IMMUNOTHERAPY-INDUCED COLITIS)

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

The Group considered the request for the off-label use of vedolizumab, up to three doses of 300mg, for the treatment of immunotherapy-induced colitis in adults who are refractory to infliximab or cases for which infliximab is contraindicated.

The Group noted that:

- immune checkpoint inhibitors are a novel class of cancer treatment that have
 improved outcomes for a subset of cancer patients. They work by antagonising
 inhibitory immune pathways, thereby augmenting immune-mediated anti-tumour
 responses. However, immune activation is not cancer-specific and often results in the
 activation of immune cells in non-cancer tissues, resulting in off-target immunemediated injury and organ dysfunction. Diarrhoea and gastrointestinal tract
 inflammation are common and sometimes serious side-effects of this type of therapy.
- the current treatment of immunotherapy-induced colitis in NHS Grampian is with oral and intravenous steroids and for some cases infliximab 5mg/kg, which is in line with the British Society of Gastroenterology (BSG) and European Society for Medical Oncology guidance
- locally off-label use of infliximab is accepted for the treatment of immunotherapy induced colitis in adults who are steroid refractory or who require early steroid sparing management
- the Service notes that vedolizumab must only be prescribed following collaboration with a senior member of the gastroenterology team and the treating oncologist, with consideration given to disease stage, symptom burden and prognosis
- unlike other 'biologic' medicines vedolizumab is only licensed for conditions of the gastrointestinal (GI) tract, e.g., ulcerative colitis, Crohn's disease and pouchitis
- vedolizumab is a monoclonal antibody that has been designed to attach to 'alfa-4-beta-7 integrin', a protein mostly found on the surface of certain white blood cells in the gut. In ulcerative colitis, Crohn's disease and pouchitis these cells are involved in causing inflammation in the gut. By blocking alfa-4-beta-7 integrin, vedolizumab reduces the inflammation in the gut and the symptoms of these diseases.
- the references provided show limited evidence of comparable efficacy for infliximab and vedolizumab used for immune-mediated diarrhoea and colitis. There are less data for vedolizumab used after infliximab/anti-TNF failure, however there is evidence in its licensed indications for efficacy in these patients.
- a systematic review with meta-analysis by Ibraheim et al. (2020) of the effectiveness
 of anti-inflammatory therapy in immune checkpoint inhibitor-induced enterocolitis
 pooled data from 1210 treated patients across 39 studies. The data for vedolizumab
 came from 50 patients from 3 studies not achieving an adequate response to
 corticosteroids, 9 had failed an anti-TNF agent. Overall, the pooled response to
 vedolizumab was 85% (95% CI 60-96).
- the use of vedolizumab (or infliximab) for immunotherapy-induced colitis is off-label, but it is a recommended option in national guidance (British Society of Gastroenterology endorsed guidance for the management of immune checkpoint inhibitor-induced enterocolitis (July 2020), and Management of toxicities from immunotherapy: ESMO Clinical Practice Guidelines for diagnosis, treatment and

follow-up (Oct 2022), and National Comprehensive Cancer Network Guidelines Version 1.2024, Management of Immune Checkpoint Inhibitor-Related Toxicities).

- Equity: vedolizumab is being used in the West of Scotland Cancer Network as part of their immunotherapy toxicity guidance, and some areas across England have vedolizumab on their formulary for this indication
- Safety: no new or unexpected safety issues identified and the gastroenterology service has experience prescribing vedolizumab
- Cost: vedolizumab is subject to a PAS discount, there is no individual patient tracking, the discount will apply to all purchases of the drug; patient numbers are expected to be small but may increase as the use of immunotherapies increases; this will be a new cost to the service, but it is a short fixed-treatment course

Members acknowledged that the availability of an additional short course 'biologic' treatment option would provide the opportunity to reduce delays in treatment, reduce hospitalisations and reduce the potential complications of immunotherapy-induced colitis. Members considered that the gut-specific mechanism of action, safety profile and effectiveness of vedolizumab could be seen to support the off-label use of vedolizumab in the management of immunotherapy-induced colitis.

The Group accepted the restricted local need for the off-label use of a short course of vedolizumab for the treatment of immunotherapy-induced colitis in adults who are refractory to infliximab or cases for which infliximab is contraindicated.

FG1 466/24 - Vedolizumab 300mg powder for concentrate for solution for infusion is routinely available in line with local guidance.

Indication under review: [off-label use] for the treatment of immunotherapy-induced colitis in adults who are steroid refractory or who require early steroid sparing management.

Restriction: for adults who are refractory to infliximab or those where infliximab is contraindicated.

It was classified 3b – licensed product available for off-label use and 8b - recommended for hospital use only.

Vedolizumab must only be prescribed following collaboration with a senior member of the gastroenterology team and the treating oncologist, with consideration given to disease stage, symptom burden and prognosis. Treatment should be administered intravenously and by qualified healthcare professionals trained to detect any infusion-related issues. Patients should be given the package leaflet.

FTEAM

Item 5.4, SMC 2654 Lonsurf® for metastatic colorectal cancer was deferred to the April meeting.

6. FORMULARY REVIEW

6.1. FORMULARY UPDATES

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

Ms Doney reported that:

- Esteve Pharmaceuticals Ltd has discontinued triamcinolone hexacetonide 20mg/1mL suspension for injection
- triamcinolone hexacetonide is a formulary medicine used for juvenile idiopathic arthritis in line with SMC advice
- · alternative steroid injections remain available
- the formulary entry will be updated to note the withdrawal

Members supported update of the formulary entry to note the discontinuation.

FTEAM

BRAND NAME CHANGES/DEBRANDING

Ms Doney reported that:

- the following formulary medicines have been debranded by the Marketing Authorisation Holders:
 - eglecaprevir/pibrentasvir 50mg/20mg coated granules in a sachet, 100mg/40mg film-coated tablets (previously Maviret®)
 - eribulin 0.88mg/2mL solution for injection (previously Halaven®)
 - ponatinib Incyte 15mg, 30mg, 45mg film-coated tablets (previously Iclusig®)
 - clozapine Mylan 25mg, 100mg tablets (previously Clozaril[®])
 - sirolimus 0.5mg, 1mg, 2mg coated tablets (previously Rapamune®)
 - conjugated Oestrogens 0.3mg, 0.625mg, 1.25mg coated tablets (previously Premarin[®])
- the entries will be updated to remove the brand name, the generic name will be noted on the formulary, and the name change highlighted to prescribers and the local and regional HEPMA Teams

FTEAM

Members supported update of the formulary entries to note the debranding.

6.2. SBAR - DAILIPORT

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

The Group considered the SBAR from the Renal Service proposing a change to the preferred brand of modified-release tacrolimus capsule to prevent organ rejection in kidney transplantation.

The Group noted that:

- Dailiport®:
 - is a once-daily tacrolimus prolonged-release preparation
 - has shown bioequivalence to an alternative once-daily tacrolimus prolonged-release preparation, Advagraf® hard capsules
- the prescribing of immunosuppressants in solid organ transplant are under the direction of a tertiary transplant centre, in this case Edinburgh Royal Infirmary
- NHS Lothian is in the process of switching to Dailiport[®]
- this would be a cost-minimising change
- Advagraf® would remain available for patients who refuse to change
- the Renal Service will co-ordinate the change, to include communication (to patients, General practices and Community Pharmacies), trough tacrolimus blood tests arranged in secondary care a week after the switch, and update of the local shared care arrangement

The Group supported the Renal Service proposal to change the preferred modifiedrelease tacrolimus capsule for the prevention of organ rejection in kidney transplantation.

SBAR - Dailiport® 0.5mg, 1mg, 2mg, 3mg, 5mg prolonged-release hard capsules (tacrolimus) is routinely available in line with local guidance. Indication under review:

- prophylaxis of transplant rejection in adult kidney or liver allograft recipients
- treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adults

It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist.

This medicinal product should only be prescribed, and changes in immunosuppressive therapy initiated, by physicians experienced in immunosuppressive therapy and the management of transplant patients.

FTEAM

SMC 402/07 - Advagraf® 0.5mg, 1mg, 3mg, 5mg prolonged-release hard capsules (tacrolimus) is not routinely available as there is a local preference for alternative medicines.

Indications under review: prophylaxis of transplant rejection in adult kidney allograft recipients.

Not routinely available as there is a local preference for alternative medicines. Note: People currently established on Advagraf® [for transplant rejection in kidney allograph recipients] may continue to receive treatment until they and their clinician consider it appropriate to stop.

FTEAM

6.3. Treatment options for dry mouth

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

The Group considered feedback from the Palliative Care Pharmacist requesting a few changes to the current formulary choices for xerostomia.

The Group noted that:

- a Short Life Working Group is looking at mouthcare NHS Grampian-wide, and work is progressing
- Bioxtra Dry Mouth Gel Mouthspray remains one of the preferred products
- Biotene Oralbalance Gel was reformulated a number of years ago with the removal of some of the "bio-active" enzymes from the original formulation
- Oralieve Moisturising Mouth Gel is an alternative product to, and is requested as a replacement for, the original formulation of Biotene Oral Balance Gel
- this is a cost-minimising change, and a ScriptSwitch message could be deployed to change prescriptions for Biotene Oralbalance Gel to Oralieve Moisturising Mouth Gel
- Oralieve Moisturising Mouth Spray is requested as an additional formulation

The Group supported the requested changes to the current formulary choices for xerostomia.

Oralieve® Moisturising Mouth Gel, Spray is routinely available in line with local guidance.

Indication under review: children, adolescents and adults age 12 years and older for the symptomatic treatment of dry mouth.

It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.

FTEAM

Biotene® Oralbalance Gel is not routinely available as there is a local preference for alternative medicines.

Indication under review: for the symptomatic treatment of dry mouth.

Not routinely available as there is a local preference for alternative medicines.

FTEAM

6.4. SBAR - METYROL® XL AND RITALIN® XL

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

The Group considered the SBAR from the Child and Adolescent Mental Health Services requesting addition of two Type 3 modified-release (MR) methylphenidate capsules to the formulary.

The Group noted that:

- there are three different types of methylphenidate MR tablets and capsules. They
 contain differing immediate-release (IR) and MR components and have differing
 durations of action.
- MR methylphenidate products should normally be prescribed by brand
- Medikinet XL is currently the only 'Type 3' MR methylphenidate capsule on the

formulary

- the addition of Metyrol[®] XL and Ritalin[®] XL offers cost-minimising prescribing options, and an alternative option for patients who are prescribed Medikinet XL but who are unable to take this preparation with food
- there is some experience prescribing these medicines, as during the shortages across a range of ADHD medications, the use of Metyrol[®] XL or Ritalin[®] XL has been recommended by specialists

The Group accepted the restricted local need for additional Type 3 MR methylphenidate capsules on the formulary, acceptance is in line with current formulary approval for Medikinet[®] XL.

SBAR - Metyrol® XL 10mg, 20mg, 30mg, 40mg, 60mg modified-release hard capsules (methylphenidate) is routinely available in line with local guidance. Indication under review: as part of a comprehensive treatment programme for attention-deficit/hyperactivity disorder (ADHD) in children and adolescents between the age of 6 and 18 years when remedial measures alone prove insufficient.

It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist.

Treatment must be initiated under the supervision of a specialist in childhood and/or adolescent behavioural disorders.

FTEAM

SBAR - Ritalin® XL 10mg, 20mg, 30mg, 40mg, 60mg modified-release hard capsules (methylphenidate) is routinely available in line with local guidance. Indication under review: as part of a comprehensive treatment programme for attention-deficit/hyperactivity disorder (ADHD) in children and adolescents between the age of 6 and 18 years when remedial measures alone prove insufficient.

It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist.

Treatment must be initiated under the supervision of a specialist in childhood and/or adolescent behavioural disorders.

FTEAM

7. Published advice

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED MARCH 2025

The Group noted the SMC advice published March 2025.

Following publication of the negative SMC recommendations, for ripretinib (Qinlock®) ▼ SMC 2722 and spesolimab (Spevigo®) ▼ SMC 2729, and the non-submission statements, for amivantamab (Rybrevant®) ▼ SMC 2768 and atezolizumab (Tecentriq®) SMC 2769, these medicine will not be included on the Grampian Joint Formulary for the indications in question.

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

- SMC 2754 cabozantinib (Cabozantinib Ipsen) (submission expected)
- SMC 2753 talazoparib (Talzenna®)

Local advice for these medicines and indications will be included in the March 2025 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'.

7.2. NATIONAL CANCER MEDICINES ADVISORY GROUP ADVICE PUBLISHED FEBRUARY 2025

The Group noted the NCMAG advice published March 2025.

The following NCMAG supported medicines have not been processed within a 60-day timescale:

- NCMAG 119 pomalidomide (submission expected)
- NCMAG 120 pomalidomide (submission expected)

Local advice for these medicines and indications will be included in the March 2025 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'.

FTEAM

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED MARCH 2025

The Group noted the SMC provisional advice issued March 2025.

If the negative SMC recommendation is published next month, this medicine will not be included on the formulary for the indication in question.

9. OTHER BUSINESS

9.1. SIGN 172 – PREVENTION AND REMISSION OF TYPE 2 DIABETES, PUBLISHED MARCH 2025

The Group noted publication of SIGN 172 Prevention and remission of type 2 diabetes.

9.2. MHRA DRUG SAFETY UPDATE: PROLONGED-RELEASE OPIOIDS: REMOVAL OF INDICATION FOR RELIEF OF POST-OPERATIVE PAIN

The Chair highlighted the March Drug Safety Article outlining the removal of the indication for the treatment of post-operative pain from the licences of all prolonged release opioids.

A member confirmed that the surgical teams do not consider this a major change as in recent years prescribing practice has moved to immediate-release opioids.

10. DOCUMENTS FOR INFORMATION

Items 10.1 (Drug Safety Update February 2025) and 10.2 (MedWatch newsletter February 2025) were noted.

11. AOCB

None.

DATE OF NEXT MEETING

Tuesday 15 April 2025 starting at 14.30 via Microsoft Teams

Signature on file

CHAIR'S SIGNATURE Dr Louise Elliot DATE 15 APRIL 2025