NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 21 April 2026 at 14:30 via Microsoft Teams

APPROVED

ITEM	SUBJECT	ACTION

WELCOME

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

1. ATTENDANCE, APOLOGIES AND DEPUTIES

Note: This item was taken later than scheduled, after item 5.1, to accommodate presenter availability.

1.1. CHAIR

Dr L Elliot, Chair.

1.2. MEMBERS PRESENT

Present	Apologies	Deputies
Mr Y Al-Obaidi	Ms L Cameron	
Mr G Burt	Mrs M Galvin	
Dr V Chieng		
Ms F Doney		
Dr L Elliot		
Mrs E Milne		
Mrs S O'Beirne		
Mr M Paterson		

1.3. IN ATTENDANCE

Ms D Bruce, Specialist Pharmacy Technician, Formulary Team.
Dr A Herrick, Consultant Rheumatologist, for item 4.
Mrs C Standen, Formulary and Medicines Management Pharmacist.

1.4. NOTES

Members who sent apologies are recorded.

To accommodate availability and time constraints, some items were taken out of order during the meeting. For clarity and consistency, these minutes are recorded in the original agenda sequence, with annotations where applicable.

2. MINUTE AND DECISIONS

2.1. DRAFT MINUTE OF THE MEETING HELD 17 MARCH 2026

Members endorsed the draft note of the meeting, pending minor typographical amendments.

The final approved minute will be made publicly available within 21 days of formal approval. **FD**

2.2. FORMULARY GROUP DECISIONS MARCH 2026 - PUBLISHED 30/03/2026

Members formally ratified the March 2026 decisions document as published.

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3. MATTERS ARISING

3.1. ACTION LOG

The Group noted the item.

3.2. SPIRONOLACTONE

At the March meeting, the Group was minded to support the off-label prescribing of spironolactone in primary care for adult females with persistent acne who had failed two courses of antibiotics, but requested clarification of the dosing regimen and required monitoring.

Following consideration of additional information provided by the service, members supported formulary inclusion, subject to development of a robust prescribing protocol (aligned with the Greater Glasgow and Clyde model) and approval by the Medicines Guidelines and Policies Group (MGPG). The maximum daily dose should be limited to 150 mg.

The Group supported prescribing in General Practice once an approved protocol is in place. Until such time, prescribing should remain within the managed service.

The Group accepted the restricted local need for the off-label use of spironolactone for the treatment of adult females with persistent acne, subject to approval of a prescribing protocol by the Medicine Guidelines and Policies Group (MGPG).

FG1 484/25 - Spironolactone 50mg, 100mg tablets is routinely available in line with local guidance.
Indication under review: [off-label use] for the treatment of adult females with persistent acne
Restriction: patients who have failed to respond to two courses of antibiotics, at least three months in duration.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. **FTEAM**

3.3. DROSPIRENONE FORMULARY ENTRY

It was confirmed that the formulary entry for drospirenone was published alongside the update to the local progestogen-only pill guidance.

4. DISCUSSION/PRESENTATION

Note: This item was taken earlier than scheduled, before item 1, to accommodate presenter availability.

4.1. DR ARIANE HERRICK, CONSULTANT RHEUMATOLOGIST, TO DISCUSS THE REQUESTS FOR BOSENTAN AND SILDENAFIL FOR SYSTEMIC SCLEROSIS

The Chair welcomed Dr Herrick, Consultant Rheumatologist to discuss the request to consider bosentan and extend the off-label use of sildenafil for adults with digital ulceration in systemic sclerosis.

Dr Herrick confirmed that:

- there is now a lot of interest in treating patients with digital ulceration quite aggressively to try and pre-empt digital ulcers or try and prevent recurrent digital ulcers
- a national pathway is available to direct treatment. Firstly, you have the treatment of Raynaud's phenomenon and then the treatment of Raynaud's phenomenon that is sufficiently severe that it has progressed to digital ulceration.

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- sildenafil is used earlier in the pathway, before bosentan, and is not licensed for digital ulceration
- bosentan is used later in the pathway, and is licensed to reduce the number of new digital ulcers in patients with systemic sclerosis and ongoing digital ulcer disease
- currently sildenafil for systemic sclerosis related Raynaud's phenomenon which has not progressed to digital ulcers tends to be prescribed nurse specialists in Aberdeen

Members' questions were addressed.

- patients with pulmonary arterial hypertension (PAH) and digital ulcers would be a very small group.
- patients with PAH would be managed by the Golden Jubilee team, and bosentan may or may not be prescribed. Patients with PAH tend to have a more vascular phenotype and so are more at risk of digital ulcers. PAH patients tend to be on several vasodilators so the local service would be reluctant to add-in anything else, e.g., bosentan, and upset the patient's vasodilation for their PAH disease. If addition of bosentan was being considered for digital ulceration this would only be done on discussion with the Golden Jubilee Team and the local service would take responsibility for prescribing.
- bosentan requires monitoring and would only be prescribed by the managed service
- local experience so far is that sildenafil at the higher [unlicensed] dose is well tolerated by patients. A few patients who would not tolerate a calcium channel blockers (CCBs) tolerate sildenafil. If it is not well tolerated, it tends to be vasodilatory side-effects and patients would stop treatment or reduced the dose.
- treatment with sildenafil is started at a low dose (25mg once or twice a day)
- sildenafil is not licensed for systemic sclerosis, but it is considered a second-line choice and would be added to or substitute a CCB, depending if the patient had a partial effect on the CCB.
- anyone with systemic sclerosis on sildenafil or bosentan would remain under the review of the specialist service
- the clinical trials of sildenafil and tadalafil have almost exclusively been in secondary Raynaud's phenomenon
- Dr Herrick confirmed that she would:
  - use off-label sildenafil for systemic sclerosis related spectrum disorders, for example, mixed connective tissue disease, undifferentiated connective tissue disease with severe digital ischaemia, and these populations would always be under hospital review
  - request the number of patients currently receiving sildenafil from the specialist service — **AH**

The Chair thanked Dr Herrick for attending the meeting to discuss the requests.
Dr Herrick left the meeting prior to the decision-making process.

5. NEW PRODUCT REQUESTS

5.1. FG1 465/24 - BOSENTAN AND SILDENAFIL (SYSTEMIC SCLEROSIS WITH ONGOING DIGITAL ULCER DISEASE)

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

The Group considered the requests for additional treatment options for the management of digital ulceration in systemic sclerosis in adults.

The Group noted that:

- bosentan:
  - is a dual endothelin receptor antagonist (ERA) with affinity for both endothelin A and B (ETA and ETB) receptors
  - as the reference product Tracleer®, was not recommended for use in NHS Scotland

for this indication due to the absence of a submission (SMC 485/08)
    - should be initiated at a dose of 62.5mg twice daily for 4 weeks then increased to the maintenance dose of 125mg twice daily
    - has a confidential contract price for the managed service
- sildenafil:
    - is a phosphodiesterase type 5 inhibitor (PDE5i) and potent vasodilator
    - is used 'off-label' for this indication
    - the recommended dose, for this indication, is 25mg to 50mg three times a day
    - is currently included on formulary [off-label] for the symptomatic management of adults with severe refractory Raynaud's phenomenon. When reviewed in 2018 it was classified as RED, hospital only. At that time, GP10 prescriptions for sildenafil required an SLS endorsement, and the off-label indication did not fit with the SLS criteria. The requirement for SLS endorsement has now been removed.
    - only the 25mg and 50mg tablets are included in the Scottish Drug Tariff (SDT)
- the *NHS England – Clinical Commissioning Policy: Sildenafil and bosentan for the Treatment of Digital Ulceration in Systemic Sclerosis in adults* concluded that there is sufficient evidence to support the routine commissioning of sildenafil and bosentan for this indication
- the Clinical Commissioning Policy includes a treatment pathway which the service plans to follow
- evidence for the off-label use of sildenafil shows that it has a positive effect on digital ulcer healing and reduction in severity of Raynaud's phenomenon in systemic sclerosis patients
- evidence for bosentan comes from two studies. In RAPIDS-1, bosentan showed a 48% reduction in the formation of new ulcers at 16 weeks compared to placebo. In RAPIDS-2, bosentan treatment was associated with a 30% reduction in new ulcer formation compared with placebo at 24 weeks, although no effect on digital ulcer healing was found.
- patient numbers for each drug are expected to be small, with some costs already in the system
- if bosentan is effective, treatment with iloprost will not be needed. Iloprost requires daily infusions for five consecutive days of each cycle, which will have additional costs for nurse/chair time and increased patient burden.

Members discussed the highly specialised nature of the disease and noted that the off-label use of sildenafil for this indication requires higher dosing regimens than that used for the licensed indication, and that primary care has no experience of these regimens.

The Group accepted the restricted local need for bosentan and sildenafil as additional treatment options for the management of adults with digital ulceration in systemic sclerosis. Sildenafil use is restricted to strengths included in the SDT.

FG1 465/24 - Bosentan 62.5mg, 125mg tablets is routinely available in line with local guidance.
Indication under review: to reduce the number of new digital ulcers in adults with systemic sclerosis and ongoing digital ulcer disease despite optimal treatment with vasodilators including oral sildenafil.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should only be initiated and monitored by a physician experienced in the treatment of systemic sclerosis. **FTEAM**

FG1 465/24 - Sildenafil 25mg, 50mg tablets is routinely available in line with local guidance.
Indication under review: [off-label use] for the treatment of adults with systemic sclerosis who have active digital ulcers despite optimal treatment with vasoldilators.

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It was classified 3b - licensed product request for unlicensed use, 8b - recommended for hospital use only. **FTEAM**

5.2. FG1SMC 2856 - GIVINOSTAT (DUCHENNE MUSCULAR DYSTROPHY)

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

The Group considered the request for givinostat suspension for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.

The Group noted:

- givinostat (Duvyzat®):
  - is a histone deacetylase inhibitor. The exact mechanism by which givinostat exerts its effect in patients with DMD is unknown.
  - [for this indication] meets SMC orphan equivalent criteria, and was accepted for use in NHS Scotland following a full submission assessed under the 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
- there are currently no curative treatments available for DMD. Corticosteroids (specifically prednisolone and deflazacort) have been shown to temporarily reduce motor function decline. Vamorolone, a synthetic corticosteroid, is also included on formulary for the treatment of DMD in line with SMC 2721.
- givinostat is a suspension administered as 2.5mL to 6mL orally twice daily with food. The recommended dose is based on body weight.
- regular monitoring is required with givinostat and the service plans for this to be undertaken by the hospital
- evidence comes from EPIDYS study, an international, double-blind, placebo-controlled, phase III study:
  - patients were randomised to givinostat twice daily in combination with corticosteroids or placebo with corticosteroids
  - the primary outcome was the mean change from baseline to month 18 in 4-stair climb. The mean change was 1.31 seconds for givinostat compared to 2.89 seconds for placebo.
- there is a lack of controlled long-term data supporting the use of givinostat beyond 18 months
- patient numbers are expected to be small and some costs are already in the system
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of givinostat

A member queried if vamorolone can be used in combination with givinostat for DMD. **FTEAM**

The Group accepted the restricted local need for givinostat for the treatment of DMD in patients 6 years of age and older who are ambulant when they initiate givinostat treatment, as outlined in SMC 2856.

FG1SMC 2856 – Givinostat 8.86mg/mL oral suspension (Duvyzat®)▼ is routinely available in line with national guidance (SMC 2856).
Indication under review: treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older who are ambulant when they initiate givinostat treatment; this includes patients who are ambulant when they initiate givinostat and become non-ambulant during treatment.
In a randomised, double-blind, phase III study, treatment with givinostat resulted in a statistically significant smaller decline in the four stairs climb time from baseline to month 18, 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

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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. **FTEAM**

5.3. FG1SMC 2764 - ABALOPARATIDE (OSTEOPOROSIS IN POST-MENOPAUSAL PEOPLE)

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

The Group considered the request for abaloparatide for the treatment of osteoporosis in postmenopausal people at very high risk of fracture.

The Group noted:

- abaloparatide:
  - activates the parathyroid hormone 1 receptor signalling pathway, stimulating osteoblastic activity and subsequently stimulating new bone formation
  - [for this indication] the recommended dose is 80micrograms once daily by subcutaneous injection. The maximum total duration of treatment should be 18 months.
  - requires assessment of blood pressure, cardiac status and electrocardiogram (ECG) prior to beginning treatment
- evidence comes from the ACTIVE study:
  - patients were randomised to abaloparatide, teriparatide or placebo for 18 months
  - the primary outcome (versus placebo): percentage of patients with one or more incidents of new vertebral fracture from the baseline spine X-rays until post-baseline spine X-rays
  - abaloparatide showed a statistically significant reduction in the incidence of new vertebral fractures versus placebo - relative risk reduction abaloparatide versus placebo = -0.88 (95%CI: -0.96 to -0.59, p<0.001)
  - ACTIVExtend - abaloparatide/placebo groups could enrol in a 24-month extension study where patients were treated for 24 months with alendronate
  - the risk reduction for new vertebral fractures, versus former placebo, remained statistically significant (-3.86 at 25 months, -4.44 at 43 months)
- indirect treatment comparison suggested there was no evidence of a difference between abaloparatide, teriparatide and romosozumab
- patient numbers are expected to be small
- the service plans to supply abaloparatide by homecare arrangement so costs will exclude VAT
- the service has stated that currently when anabolic therapy is being considered and romosozumab is deemed inappropriate, teriparatide is currently offered. Teriparatide would remain the first-choice for most cases, but abaloparatide may be selected when there is a high risk of hip and vertebral fracture and would also be offered instead of teriparatide if there have been side-effects to teriparatide.
- once a pen device is started it does not need to be refrigerated, which may be advantageous for patients
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of abaloparatide

The Group accepted the restricted local need for abaloparatide for the treatment of osteoporosis in postmenopausal people with a very high risk of fracture, as outlined in SMC 2764.

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	FG1SMC 2764 - Abaloparatide 80micrograms solution for injection in pre-filled pen (Eladynos®)▼ is routinely available in line with national guidance (SMC 2764). Indication under review: treatment of osteoporosis in postmenopausal people at very high risk of fracture, assessed using a validated fracture risk assessment tool. In a randomised double-blind phase III study, abaloparatide was associated with a statistically significant reduction in the incidence of new vertebral fractures versus placebo. **This advice applies only in the context of approved NHS Scotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/list prices that are equivalent or lower.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.**	**FTEAM**

5.4. FG1SMC 2848 - GUSELKUMAB (ULCERATIVE COLITIS)

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

The Group considered the request for guselkumab as an additional treatment option for the treatment of adults with moderately to severely active ulcerative colitis (UC).

The Group noted:

- guselkumab is a fully human immunoglobulin G1 lambda (IgG1λ) monoclonal antibody that binds to interleukin 23
- the formulary includes two other IL-23 inhibitors, risankizumab and mirikizumab, for the treatment of adults with moderately to severely active UC
- guselkumab induction is administered as either 200mg by intravenous (IV) infusion or 400mg subcutaneous (SC) injection at weeks 0, 4 and 8, then maintenance dose of 100mg SC every 8 weeks. A maintenance dose of 200mg SC every 4 weeks can be considered for patients who do not show adequate therapeutic benefit to induction treatment.
- guselkumab is already included on the formulary for the treatment of Crohn's disease
- evidence for UC comes from QUASAR and ASTRO, randomised, phase III, double-blind, placebo-controlled, parallel-group studies:
- the primary outcome was clinical response at week 12 (induction) and week 44 (maintenance, QUASAR only).
- in QUASAR:
  - the clinical response at week 12 was 22.6% (n=95/421) for guselkumab 200mg IV induction versus 7.9% (n=22/280) for placebo
  - the clinical remission at week 44 was 45.2% (n=85/188) for guselkumab 100mg every 8 week SC versus 50% (n=95/190) for guselkumab 200mg every 4 weeks SC versus 18.9% (n=36/190) for placebo
- in ASTRO the clinical response at week 12 was 27.6% (77/279) for guselkumab 400mg SC induction versus 6.5% (n=9/139) for placebo
- a network meta analysis comparing the efficacy and safety of guselkumab compared to risankizumab and mirikizumab showed similar clinical benefit
- patient numbers are expected to be small, but will be cumulative
- cost off-set will be available as patients would have been treated with an alternative biologic agent
- the service plans to supply guselkumab by a homecare arrangement so costs will exclude VAT
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of guselkumab

The Group accepted the restricted local need for guselkumab as an additional treatment option for the treatment of adults with moderately to severely active UC, as outlined in SMC 2848.

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	FG1SMC 2848 - Guselkumab 200mg/2mL concentrate for solution for infusion, 100mg/1mL, 200mg/2mL solution for injection pre-filled pen (Tremfya®) is routinely available in line with national guidance (SMC 2848). **Indication under review: for the treatment of adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, biologic treatment, or a Janus kinase (JAK) inhibitor.** **Guselkumab offers an additional treatment choice in the therapeutic class of interleukin inhibitors in this setting.** **This advice applies only in the context of approved NHS Scotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/list prices that are equivalent or lower.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. This medicinal product is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which it is indicated.**	**FTEAM**

5.5. FG1SMC 2800 - ALYFTREK® (CYSTIC FIBROSIS, 6 YEARS AND OLDER)

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

The Group considered the request for Alyftrek® a new triple-combination cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy.

The Group noted:

- Alyftrek®:
  - contains the ingredients vanzacaftor, tezacaftor and deutivacaftor
  - was accepted by SMC following an abbreviated submission. Medicines reviewed under the SMC abbreviated submission process are estimated to have a limited net budget impact and resource allocation across NHS Scotland.
- other CFTR modulators are accepted for use in NHS Scotland following SMC collaboration with NICE on TA988
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of Alyftrek®

The Group accepted the restricted local need for Alyftrek® as an additional treatment choice in the therapeutic class of CFTR modulators.

	FG1SMC 2800 - Alyftrek®▼ 50mg/20mg/4mg, 125mg/50mg/10mg film-coated tablets (deutivacaftor/tezacaftor/vanzacaftor) is routinely available in line with national guidance (SMC 2800). **Indication under review: for the treatment of cystic fibrosis (CF) in people aged 6 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.** **This advice applies only in the context of approved NHS Scotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/list prices that are equivalent or lower.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.** **Alyftrek® should only be prescribed by healthcare professionals with experience in the treatment of CF. If the person with CF has an unknown genotype, an accurate and validated genotyping method should be performed to confirm the presence of at least one F508del mutation or another responsive mutation.**	**FTEAM**

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6. FORMULARY REVIEW

6.1. FORMULARY UPDATES

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

DEBRANDING

Ms Bruce reported that:
- Budenofalk® suppositories has been de-branded and will now be known as Budesonide Dr. Falk Pharma 4mg suppositories
- Xospata® tablets has been de-branded and will now be known as Gilteritinib Astellas 40mg film-coated tablets

The formulary entries will be updated to remove the brand names, and the name changes highlighted to the local and regional Hospital Electronic Prescribing and Medicines Administration (HEPMA) Teams.

Members supported update of the formulary entries to remove the brand name, only the generic name will be noted on the formulary. **FTEAM**

DISCONTINUATIONS

Ms Bruce reported that the following medicines were being discontinued:
- teriflunomide as the brand Aubagio®, and multiple generic preparations are available
- conestat alfa 2,100 units powder (and solvent) for solution for injection (Ruconest®)
- procyclidine 10mg/2mL solution for injection ampoules

Members supported update of the formulary to note the discontinuations. **FTEAM**

6.2. BIOSIMILAR CONTRACT CHANGES

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

Ms Bruce reported that, following recent contract reviews, several products are now available as biosimilar medicines, and services have requested that these products are considered for inclusion on the formulary.

The Group noted that:
- biosimilar products are considered outwith remit for the SMC, selection of biosimilar to replace reference products is determined locally
- switching to a biosimilar product is cost-minimising for the NHS
- recent contract reviews include a change to the current preferred etanercept biosimilar and the availability of new biosimilar products for denosumab (60mg), golimumab and omalizumab, which are now off-patent

Members acknowledged the potential benefits of the introduction of biosimilar medicines.

The Group accepted the restricted local need for new biosimilar choices for specific service areas. Use was supported within established treatment pathways for appropriate patients, as identified by treating clinicians, and in accordance with the biosimilar prescribing framework.

The requests were supported without the need for full submissions. It was agreed that the biosimilar products will be added to the formulary, aligned with the existing formulary acceptance, subject to the products' current licensing status.

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	Denosumab 60mg/mL solution for injection in pre-filled syringe (Stoboclo®)▼ is routinely available in line with local guidance. **Indication under review: in line with current formulary acceptance for the reference product Prolia®.** **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. Administration should be performed by an individual who has been adequately trained in injection techniques.**	**FTEAM**
	Etanercept 25mg, 50mg solution for injection in pre-filled pen/syringe (Erelzi®)▼ is routinely available in line with local guidance. **Indication under review: in line with current formulary acceptance for etanercept used in the adult rheumatology service.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which it is indicated. Patients should be given the Patient Card.**	**FTEAM**
	Golimumab 50mg, 100mg solution for injection in pre-filled pen/syringe (Gobivaz®) ▼ is routinely available in line with local guidance. **Indication under review: in line with current formulary acceptance for golimumab used in the adult rheumatology service.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of conditions for which it is indicated. Patients should be given the Patient Card.**	**FTEAM**
	Omalizumab 75mg, 150mg solution for injection in pre-filled pen/syringe (Omlyclo®) ▼ is routinely available in line with local guidance. **Indication under review: in line with current formulary acceptance for the reference product Xolair®.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated by physicians experienced in the diagnosis and treatment of conditions for which it is indicated.**	**FTEAM**
	Biological medicines, including biosimlar 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. SBARS MELATONIN

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

The Group considered the requests from the Community Child Health (CCH) and Child and Adolescent Mental Health Services (CAMHS) requesting additional formulations of melatonin and changes to the formulary entry for melatonin.

The Group noted that:

- melatonin:
  - is included on the formulary and prescribed in Primary Care on the recommendation of a consultant specialist for the treatment of sleep disorders in children and adolescents over 3 years of age and adults with neurodevelopmental disorders including ADHD (attention deficit hyperactivity disorder), autism spectrum disorder (ASD), global developmental delay or visual impairment, who have chronic sleep disturbance
  - immediate-release 3mg is the first-line choice, with modified-release 2mg used off-

label second-line; both formulations are included in the Scottish Drug Tariff (SDT)

- there are no oral solutions currently included on the formulary, and the service is requesting addition of additional preparations for people who cannot swallow solid oral dosage forms
- melatonin 1mg/mL sugar free oral solution is included in Part 7 of the SDT. However, the service notes that prescribing liquid melatonin generically in people under 18 years can be challenging due to the varying excipient profiles of available products.
- the service's preferred formulations for people who cannot swallow tablets are:
  - Adaflex® tablets, which may be swallowed whole or are licensed to be crushed and mixed with water directly before administration. When dissolved Adaflex® has a favourable excipient profile in comparison to liquid melatonin preparations.
  - Adaflex® is available in strengths of 1mg, 2mg, 3mg, 4mg, 5mg strengths (all priced at £10.89 per pack of 30 tablets) which allows flexibility in dose selection, including a lower starting dose.
  - Ceyesto® 1mg/mL oral solution, which has a more favourable excipient content profile for people under 18 years. This may be appropriate for people who are unable to tolerate Adaflex® dissolved in water. While generic sugar-free oral solution is listed in Part 7 of the SDT (£10.94 for 150mL), Ceyesto® is more expensive (£17.10 per 100mL; £25.65 per 150mL).
- that branded prescribing would be needed to ensure the people receive the preferred preparations

Members acknowledged that there was a need for additional preparations for people that cannot swallow solid oral dosage forms. However, noting the higher cost compared with options listed in the SDT, members requested additional information on the excipient profile of Ceyesto® and its particular benefits in those under 18 years. **FTEAM**

The Group accepted the restricted local need for Adaflex® as an additional formulation of melatonin for people under 18 years who cannot swallow solid oral dosage forms.

SBAR - Melatonin 1mg, 2mg, 3mg, 4mg, 5mg tablets (Adaflex®) is routinely available in line with local guidance.
Indication under review: in line with current formulary acceptance for melatonin.
Restriction: to patients who cannot swallow solid oral dosage forms.
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 should be initiated by physicians experienced in ADHD and/or paediatric sleep medicine. **FTEAM**

SBAR - Melatonin 1mg/mL oral solution (Ceyesto®) decision deferred to future meeting
Indication under review: in line with current formulary acceptance for melatonin.
Restriction: to patients who cannot swallow solid oral dosage forms and are unable to tolerate Adaflex®.
Decision deferred to future meeting **FTEAM**

REQUEST FOR CHANGE IN FORMULARY CLASSIFICATION

The Group discussed the request to change the formulary classification of melatonin to allow prescribing in primary care, subject to a prescribing protocol, without the need for (re-)referral to the specialist service.

Members noted that, although general practice is familiar with melatonin, there is variation in prescribing practice. The change in classification could potentially widen access to prescribing for children and young people that are not under the care of the

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specialist services. In addition, there has been an increase in private diagnosis of ADHD, and clarity is required in relation to non-NHS prescribing requests.

Whilst acknowledging that prescribing guidance would be helpful, the Group agreed that the SBAR should be revised. Further information is required before a change in formulary classification can be considered, and review of the revised SBAR by other decision-making groups would be beneficial. **FTEAM**

6.4. SBAR GUANFACINE

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

The Group considered the SBAR submitted by CAMHS requesting review of the formulary entry for guanfacine.

The Group noted that:
- guanfacine is included on the formulary as a third-line treatment option for ADHD
- prescribing of guanfacine is recommended by specialist prescribers within CAMHS and CCH
- Intuniv® is the reference product for guanfacine prolonged-release tablets, which is available in strengths up to 4mg, doses up to the maximum licensed daily dose of 7mg necessitates patients taking multiple tablets
- guanfacine prolonged-release tablets are now available generically, with the generic available in additional in the strengths of 5mg, 6mg and 7mg
- the MHRA Public Assessment Report confirms bioequivalence between the generic product and Intuniv®
- there are no changes requested to the formulary classification or indication

The Group supported changing the formulary to the record the entry generically and accepted the restricted local need for addition strengths of guanfacine prolonged-release tablets to reduced pill burden at higher doses.

SBAR - Guanfacine 1mg, 2mg, 3mg, 4mg, 5mg, 6mg, 7mg prolonged-release tablets is routinely available in line with local guidance.
Indication under review: for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.
Guanfacine must be used as a part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.
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 an appropriate specialist in childhood and/or adolescent behavioural disorders.

6.5. SBAR METHYLPHENIDATE

FTEAM

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

The Group considered the SBAR submitted by CAMHS requesting inclusion of a new chewable formulation of methylphenidate prolonged-release tablets.

The Group noted that:
- Tuzulby® is a newly licensed modified-release methylphenidate formulation and the first chewable prolonged-release methylphenidate tablet available in the UK. It contains a 30% immediate-release and 70% prolonged-release component, providing approximately 8 hours of symptom control.
- current formulary modified-release methylphenidate options with a similar duration of

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action, Equasym XL® and Medikinet XL®, must be swallowed whole or administered by opening capsules and swallowing intact beads. Many children and young people struggle to do this reliably due to sensory sensitivities, oral-motor challenges, or anxiety. This leads to erratic dosing, distress, poor adherence, or the need to resort to the use of off-label crushed immediate-release tablets or consideration of more expensive non-formulary liquid formulations, which both requiring twice daily dosing to achieve an eight-hour duration of action.

- Tuzulby® offers a suitable, once-daily modified-release alternative for this patient cohort
- the introduction of Tuzulby® is would be cost-neutral to cost-minimising
- branded prescribing would be needed to ensure that people receive the preferred preparation

The Group accepted the restricted local need for Tuzulby®, a chewable prolonged-release methylphenidate preparation, as an additional preparation for patients with swallowing difficulties.

SBAR - Methylphenidate 20mg, 30mg, 40mg prolonged-release chewable tablets (Tuzulby®) 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 6-17 years old when remedial measures alone prove insufficient.
In line with current formulary acceptance for methylphenidate modified release preparations.
Restriction: patients who:

- **cannot swallow capsules whole**
- **cannot tolerate capsule beads due to sensory, developmental or oral-motor difficulties**
- **would otherwise require off-label crushed immediate-release methylphenidate or non-formulary liquid formulations, or to move to a second- or third-line ADHD medication option, without adequate trial of first-line methylphenidate**

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

6.6. ADDITIONAL ITEM – PREFERRED BRAND OF TESTOSTERONE UNDECANOATE

An item not included on the agenda was raised.

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

Ms Doney reported that colleagues in the Medicines Management Team and the Endocrinology Service have identified a clinically equivalent cost efficiency and requested that Roxadin® be recorded as the preferred long-acting testosterone undecanoate 100mg/4mL preparation.

The Group accepted the request to record Roxadin® (100mg/4mL) as the preferred preparation, without the need for a full submission.

Testosterone undecanoate 1000mg/4mL solution for injection (Roxadin®) is routinely available in line with local guidance.
Indication under review: testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests
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.

FTEAM

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7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED APRIL 2026

The Group noted the SMC advice published April 2026.

Following publication of the negative SMC recommendation for dostarlimab (Jemperli®▼ - SMC 2828) and the non-submission statements for baloxavir marboxil (Xofluza® - SMC 2920), baloxavir marboxil (Xofluza® - SMC 2921), and eszopiclone (Lunivia®▼ - SMC 2922) these medicines 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 2893 acalabrutinib (Calquence®) (submission received)
- • SMC 2833 nemolizumab (Nemluvio®)▼ (submission expected)
- • SMC 2815 osimertinib (Tagrisso®) (submission expected)
- • SMC 2829 pembrolizumab (Keytruda®) (submission received)
- • SMC 2923 sotatercept (Winrevair®)▼

Local advice for these medicines and indications will be included in the April 2026 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 APRIL 2026

The Group noted the SMC provisional advice issued April 2026.

If the SMC issues negative recommendations or non-submission statements next month, these medicines will not be included on the formulary for the specified indications.

8.2. NATIONAL CANCER MEDICINES ADVISORY GROUP ADVICE ISSUED MARCH 2026

The Group noted the NCMAG provisional advice issued March 2026.

If NCMAG issues not supported statements next month, these medicines will not be included on the formulary for the specified indications.

9. OTHER BUSINESS

9.1. QUALITY PRESCRIBING FOR CHRONIC PAIN: GUIDE FOR IMPROVEMENT 2026-2029

The Group noted the item.

10. DOCUMENTS FOR INFORMATION

Items 10.1 (MHRA Safety Round-up March 2026), 10.2 (MedWatch Vol.7 Issue 1 March 2026), 10.3 (Shared Learning Points Wrong Patient Administration January 2026) and 10.5 (Grampian Primary Care Prescribing Group meeting minute January 2026), were noted.

ITEM 10.4 GRAMPIAN ANTIMICROBIAL MANAGEMENT TEAM MEETING MINUTE FEBRUARY 2026

Ms Doney reported that continued funding for the Right Decisions platform has been confirmed, and the Grampian Area Drug and Therapeutics Committee (GADTC) has approved the request to host the 'Alert' antimicrobial guidance solely on the Right Decisions app.

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11. AOCB

None.

DATE OF NEXT MEETING

Tuesday 19 May 2026 starting at 14.30 via Microsoft Teams.

Signature on file

CHAIR'S SIGNATURE **Fiona Doney** **DATE** **19 May 2026**