

PROTECTIVE MARKING: NONE

**NHS GRAMPIAN**  
**Minute of Formulary Group Meeting**  
**Tuesday 17 October 2023 at 14:30 via Microsoft Teams**

**PRESENT**

Ms L Cameron  
Dr V Chieng  
Dr D Culligan  
Ms A Davie  
Ms F Doney (Vice-Chair)  
Dr L Elliot (Chair)  
Mrs S Howlett  
Mrs G McKerron  
Mr M Paterson  
Mr R Sivewright

**APOLOGIES**

Miss R Anderson  
Dr M Metcalfe (Vice-Chair)  
Mrs E Milne

**APPROVED**

**IN ATTENDANCE**

Mrs Christine Standen, Formulary and Medicines Management Pharmacist.

<b>ITEM</b>	<b>SUBJECT</b>	<b>ACTION</b>
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WELCOME

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

**1. APOLOGIES**

Apologies for absence were requested and noted.

**2. DRAFT MINUTE OF THE MEETING HELD 19 SEPTEMBER 2023**

The Group 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**

**3. PRESENTATION/DISCUSSION**

None.

**4. MATTERS ARISING**

**4.1. ACTION LOG**

The action log was noted.

No additional items were identified for discussion at the meeting.

**4.2. FG1 455/22 - RIVAROXABAN (PREVENTION OF ATHEROTHROMBOTIC EVENTS IN PAD)**

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

At the September meeting members agreed that treatment reduces morbidity and mortality but at an increased risk of bleeding. It was felt that a protocol was needed to support prescribing and members posed some additional questions to the requestor/service.

Replies to the questions were sent by email the day before the meeting.

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ITEM	SUBJECT	ACTION
	<p>Mrs Standen provided members with a summary of the replies:</p> <ul style="list-style-type: none"><li>• the service does not plan to use rivaroxaban in combination with dual antiplatelet therapy. This is in line with the COMPASS regimen which comprised of low dose rivaroxaban and aspirin only.</li><li>• the service does not feel that a protocol is necessary, as low dose rivaroxaban can be well tolerated [in advanced ages, weight loss or mild kidney function deterioration]. Treatment is always started by the vascular service and guidance for Primary Care is included in the patient's discharge letter. All patients [undergoing a vascular procedure] are reviewed at an outpatient clinic 6-12 weeks' postoperatively and the Vascular Unit is reluctant to prescribe this regimen if the patient's eGFR (estimated glomerular filtration rate) is lower than 40mL/min/1.73m<sup>2</sup>.</li><li>• the current direct oral anticoagulant (DOAC) guidance does not include this regimen and its prophylactic indication, but the requestor/service would be glad to be involved in creating an addendum to the current guidance</li><li>• there are patients already on treatment and the service plans to conduct a local audit to analyse the benefits and risks for these patients</li><li>• there are no specific leaflets given to patients', but patients' are counselled by the ward pharmacists and given the manufacturer's booklet. Patients are given specific warnings regarding gastro-intestinal bleeding.</li></ul>	
	<p>Members noted that treatment is always started by the vascular service but considered that the expectations of Primary Care, for ongoing review and monitoring, were not clear. There were concerns that information may not always be available in discharge documents, including the initial anticipated duration of treatment.</p>	
	<p>Members agreed that an addendum to the current DOAC guidance [for low-dose rivaroxaban plus aspirin] for this indication was appropriate and felt that this should be available to allow acceptance to the formulary.</p> <p>Members agreed that people currently established on treatment should continue to receive treatment until they and their clinician consider it appropriate to stop.</p>	
	<p>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.</p> <p>However, 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.</p>	
	<p><b>Members deferred publication of the decision pending MGPG approval of an addendum to the current DOAC guidance.</b></p>	<b>FTEAM</b>
	<p><b>4.3. DARATUMUMAB COSTS (FOR INFO)</b></p>	
	<p>At the September meeting members discussed the significant cost of daratumumab in combination with lenalidomide and dexamethasone for newly diagnosed multiple myeloma.</p>	
	<p>Ms Doney shared the confidential costs of the different indications/lines of treatment.</p>	
	<p><b>4.4. FORMULARY GROUP SURVEY</b></p>	
	<p>Mrs Standen reminded members that the survey of the format, content and presentation of the information provided for Formulary Group meetings closes 24<sup>th</sup> October.</p>	

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ITEM	SUBJECT	ACTION
5.	<b>FORMULARY GROUP DECISIONS SEPTEMBER 2023 - PUBLISHED 02/10/2023</b> Members ratified the decisions of the September 2023 meeting as published.	
6.	<b>FORMULARY REVIEW</b>	
	<b>6.1. DISCONTINUATIONS</b>	
	There were no declarations of interest recorded in relation to these products.	
	The Group reviewed the Formulary Team's summary document highlighting some discontinued medicines.	
	The Group supported the changes proposed by the Formulary Team:	
	<ul style="list-style-type: none"><li>• minor change to the current website entry for the non-formulary medicine racecadotril (10mg granules (Hidrasec Infants®), 30mg granules (Hidrasec Children®), 100mg capsules (Hidrasec®)), amend to note that this product is now withdrawn from use/discontinued</li></ul>	FTEAM
	<ul style="list-style-type: none"><li>• create an entry for testosterone 50mg/g gel (Testim®) noting its withdrawal; the MAH is exiting the UK market with the last shipments expected to be made November 2023</li></ul>	FTEAM
	<ul style="list-style-type: none"><li>• minor change to the current website entry for the formulary medicine lixisenatide 20micrograms/0.2mL (Lyxumia®), amend to note that this product will be discontinued December 2023</li></ul>	FTEAM
	<b>6.2. AZATHIOPRINE TABLETS (NEW STRENGTHS)</b>	
	There were no declarations of interest recorded in relation to this product.	
	Ms Doney reported that:	
	<ul style="list-style-type: none"><li>• azathioprine tablets are included on the Scottish Drug Tariff (SDT) and formulary as 25mg and 50mg tablets</li><li>• prescribers and patients are acquainted with the established strengths and the new strengths pose a risk for prescribers, dispensers and patients (risk of overdose if patients receive (prescribed, dispensed or administered) or take the wrong dose)</li><li>• there is no antidote for azathioprine overdose, and overdose will most likely result in bone marrow suppression</li><li>• at current prices, costs do not favour the new strengths, being at least 15p to 20p more per dose for 75mg or 100mg doses respectively</li><li>• the benefit would be reduced pill burden</li></ul>	
	The Group agreed that the risks of introduction outweigh the benefits, and supported the recommendation to record azathioprine 75mg and 100mg tablets as 'non-formulary'.	
	<b>Azathioprine 75mg, 100mg tablets is not routinely available in NHS Grampian.</b>	
	<b>Indication under review: azathioprine is indicated:</b>	
	<ul style="list-style-type: none"><li>• <b>in immunosuppressive regimens as an adjunct to immunosuppressive agents that form the mainstay of treatment (basic immunosuppression)</b></li><li>• <b>in combination with other immunosuppressive agents for the prophylaxis of transplant rejection in patients receiving allogenic kidney, liver, heart, lung, or pancreas transplants</b></li><li>• <b>either alone or in combination with corticosteroids and/or other drugs and procedures in severe cases of the following diseases, in patients who are intolerant to steroids or who are dependent on steroids and in whom the therapeutic response is inadequate despite treatment with high doses of steroids:</b><ul style="list-style-type: none"><li>▪ <b>Severe active rheumatoid arthritis that cannot be kept under control by less toxic agents (disease modifying anti-rheumatic drugs, DMARDs)</b></li><li>▪ <b>Severe or moderately severe inflammatory intestinal disease (Crohn's</b></li></ul></li></ul>	

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	disease or ulcerative colitis) ▪ <b>Systemic lupus erythematosus</b> ▪ <b>Dermatomyositis</b> ▪ <b>Auto-immune chronic active hepatitis</b> ▪ <b>Polyarteritis nodosa</b> ▪ <b>Refractory warm auto-immune haemolytic anaemia</b> ▪ <b>Chronic refractory idiopathic thrombocytopenic purpura</b>	
	<b>Not recommended for use within NHS Grampian.</b>	<b>FTEAM</b>

**6.3. SUNSCREEN PREPARATIONS**

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

Ms Doney reported that:

- the Advisory Committee on Borderline Substances (ACBS) list in the BNF (British National Formulary) has been updated, adding Anthelios® Sunscreen Lotion SPF 50+ and removing Sensense® Ultra lotion SPF 50+ due to its withdrawal
- sunscreen preparations should be prescribed in line with ACBS approved indications
- sunscreens marked as ACBS in the British National Formulary are regarded as drugs when prescribed for skin protection against ultraviolet radiation in abnormal cutaneous photosensitivity resulting from genetic disorders or photodermatoses

The Group supported aligning the formulary choice of sunscreens with the revised ACBS list.

**Anthelios® Sunscreen Lotion SPF 50+ is routinely available in line with national guidance ([ACBS](#)).**

**Indication under review: in line with recommendations of the ACBS, when prescribed for skin protection against ultraviolet radiation and/or visible light in abnormal cutaneous photosensitivity causing severe cutaneous reactions in genetic disorders (including xeroderma pigmentosum and porphyrias), severe photodermatoses (both idiopathic and acquired) and in those with increased risk of ultraviolet radiation causing adverse effects due to chronic disease (such as haematological malignancies), medical therapies and/or procedures.**

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

**FTEAM**

The formulary entry for Sensense® Ultra (SPF 50+ lotion) will be changed, noting that this preparation has been discontinued/removed from the BNF list of products available under ACBS for photodermatoses.

**FTEAM**

**7. OTHER BUSINESS**

**7.1. PHARMACY FIRST**

Ms Doney confirmed that the updated Pharmacy First Approved List came into force on 1st October, and the Formulary Team is working to check that the formulary entries are in line with the latest Approved List.

**FTEAM**

**8. NEW PRODUCT REQUESTS**

**8.1. FGA 453/22 - METHENAMINE (PROPHYLAXIS OF RECURRENT URINARY TRACT INFECTIONS IN ADULTS)**

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

The Group considered the request from the Urology Service for methenamine tablets for the prophylaxis of recurrent urinary tract infections (UTIs) in adults.

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ITEM	SUBJECT	ACTION
	<p>The Group noted that:</p> <ul style="list-style-type: none"><li>• methenamine hippurate:<ul style="list-style-type: none"><li>▪ is considered outwith SMC remit as it was licensed prior to the inception of SMC</li><li>▪ is a urinary antiseptic</li><li>▪ would be a non-antibiotic alternative to prophylactic antibiotics and support the aims of antibiotic stewardship (e.g., reducing anti-microbial resistance and side effects of antibiotics)</li><li>▪ is given orally at a dose of 1g twice a day. In patients with catheters the dosage may be increased to 1g three times a day.</li></ul></li><li>• the Antimicrobial Management Team (AMT) supports the formulary application</li><li>• treatment can be given indefinitely but the service proposes that patients should be reviewed every six months</li><li>• evidence comes from ALTAR, which evaluated the effectiveness of methenamine for recurrent UTI prevention in women</li><li>• in ALTAR:<ul style="list-style-type: none"><li>▪ the primary objective was to determine if methenamine hippurate was non-inferior to antibiotic prophylaxis in reducing symptomatic antibiotic treated UTI incidence in women with recurrent UTIs over a 12-month treatment period</li><li>▪ the incidence of symptomatic, antibiotic treated UTIs was 0.89 episodes per person year in the antibiotic prophylaxis group and 1.38 episodes per person year in the methenamine hippurate group, with an absolute difference of 0.49 (90% confidence interval 0.15 to 0.84) confirming non-inferiority</li></ul></li><li>• the cost of methenamine hippurate is higher than the antibiotics used for UTI prophylaxis</li></ul>	
	<p>Members noted the higher cost of treatment for methenamine hippurate, but accepted that it was important to support the aims of antimicrobial stewardship and reduce antibiotic use.</p>	
	<p>The Group supported the restricted local need for methenamine hippurate for the prophylaxis of recurrent UTIs, with different formulary classifications for its use in women [GREEN] compared to its use in men or adults with indwelling catheters [AMBER 1].</p>	
	<p>Members agreed it was important to highlight this change in practice for the treatment of uncomplicated UTI in women. Particularly when to prescribe methenamine hippurate in preference to antibiotic prophylaxis, as prescribers first thought for prophylaxis remains trimethoprim or nitrofurantoin.</p>	
	<p>To support the potential first-line use of methenamine hippurate for women the Group requested that the AMT update its Primary Care prescribing guidance and provide supporting information for prescribers.</p>	<b>AMT</b>
	<p><b>FG1 453/22 - Methenamine hippurate 1g tablets is routinely available in line with local guidance.</b></p> <p><b>Indication under review: the prophylaxis of recurrent urinary tract infections in adult women as long-term therapy in the prevention of recurrent cystitis.</b></p> <p><b>It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.</b></p>	<b>FTEAM</b>
	<p><b>FG1 453/22 - Methenamine hippurate 1g tablets is routinely available in line with local guidance.</b></p> <p><b>Indication under review: the prophylaxis of recurrent urinary tract infections in adults:</b></p> <ul style="list-style-type: none"><li>• <b>as long-term therapy in the prevention of recurrent cystitis</b></li><li>• <b>to suppress urinary tract infection in patients with indwelling catheters and to reduce the incidence of catheter blockage</b></li></ul>	

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ITEM	SUBJECT	ACTION
	<b>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.</b>	<b>FTEAM</b>

**8.2. SMC 2519 - NIVOLUMAB (FIRST-LINE TREATMENT OF UNRESECTABLE ADVANCED, RECURRENT OR METASTATIC OESOPHAGEAL SQUAMOUS CELL CARCINOMA (OSCC))**

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

The Group considered the request for nivolumab, in combination with fluoropyrimidine- and platinum-based combination chemotherapy, for the first-line treatment of adults with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma (OSCC) with tumour cell programmed death ligand 1 (PD-L1) expression  $\geq 1\%$ .

The Group noted that:

- nivolumab:
  - 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
  - [for this indication] is administered as an intravenous infusion at a dose of 240mg every 2 weeks or 480mg every 4 weeks [in combination with fluoropyrimidine- and platinum-based chemotherapy]
  - [for this indication] treatment is recommended until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression
- evidence comes from CheckMate 648:
  - the median overall survival (OS) was 15 months versus 9.1 months and the median progression-free survival (PFS) was 6.9 months versus 4.4 months for nivolumab plus chemotherapy and chemotherapy alone
  - the median duration of treatment was 5.7 months
- pembrolizumab is included on the formulary, in combination with platinum- and fluoropyrimidine-based chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic carcinoma of the oesophagus or human epidermal growth factor receptor 2 (HER2) negative gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a combined positive score (CPS) $\geq 10$
- the Marketing Authorisation Holder (MAH) conclusion from an indirect comparison was that nivolumab plus chemotherapy and pembrolizumab plus chemotherapy have similar OS and PFS
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of nivolumab

The Group accepted the restricted local need for nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy for the first-line treatment of adults with unresectable advanced, recurrent or metastatic OSCC with tumour cell PD-L1 expression  $\geq 1\%$ , as outlined in SMC 2519.

**SMC 2519 - Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) is routinely available in line with national guidance (SMC 2519).**

**Indication under review: in combination with fluoropyrimidine- and platinum-based combination chemotherapy for the first-line treatment of adults with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma (OSCC) with tumour cell programmed death ligand 1 (PD-L1) expression  $\geq 1\%$ .**

**Addition of nivolumab to fluoropyrimidine- and platinum-based combination chemotherapy significantly increased overall and progression-free survival in patients receiving first-line treatment for advanced, recurrent or metastatic OSCC with PD-L1 expression  $\geq 1\%$ .**

<b>ITEM</b>	<b>SUBJECT</b>	<b>ACTION</b>
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**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.**

**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 must be initiated and supervised by physicians experienced in the treatment of cancer. Patient selection for treatment with nivolumab based on the tumour expression of PD-L1 should be confirmed by a validated test.**

**FTEAM**

**8.3. NCMAG 110 - ABIRATERONE (OFF-LABEL USE, NEWLY DIAGNOSED LOW-RISK METASTATIC HORMONE-SENSITIVE PROSTATE CANCER)**

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

The Group considered the request for the off-label use of abiraterone in combination with prednisolone and androgen deprivation therapy for the treatment of newly diagnosed low-risk metastatic hormone-sensitive prostate cancer patients who are not suitable for currently accessible on-label alternatives.

The Group noted that:

- abiraterone:
  - [for this indication] is taken once-daily at a dose of 1,000mg with 5mg prednisolone
  - is already included on the formulary for prostate cancer in the metastatic and non-metastatic settings
- during COVID-19, National Cancer Medicines Advisory Group (NCMAG) supported the use of abiraterone plus prednisolone in newly diagnosed low-risk metastatic hormone-sensitive prostate cancer in combination with androgen deprivation therapy, in patients who would otherwise receive docetaxel. When enzalutamide was accepted for use in NHS Scotland for metastatic hormone-sensitive prostate cancer this COVID-19 advice was withdrawn.
- last year enzalutamide and apalutamide were accepted for use in NHS Scotland and included on the formulary for the treatment of adults with metastatic hormone-sensitive prostate cancer in combination with androgen deprivation therapy
- NCMAG 110 supports the off-label use of abiraterone in patients not suitable for currently accessible on-label alternatives
- evidence comes from the 'abiraterone comparison' study within the STAMPEDE trial, which showed overall survival (% alive at 5 years) in patients with low-risk metastatic hormone-sensitive prostate cancer was 55% versus 72% for ADT only versus ADT plus abiraterone/prednisolone
- abiraterone is now available generically at a confidential contract price
- enzalutamide and apalutamide are subject to PAS arrangements
- in comparison to enzalutamide and apalutamide, abiraterone requires more blood monitoring initially; every 2 weeks for 3 months and then monthly thereafter compared to monthly
- this will be a new cost to the service

Members discussed the use of abiraterone for newly diagnosed low-risk metastatic hormone-sensitive prostate cancer noting that the NCMAG advice supported use only in adults who are not suitable for currently accessible on-label alternatives.

A member questioned if there was a potential to allow the specialist service to consider use for all low-risk patients. Ms Doney to investigate.

**FD**

The Group accepted the restricted local need for the off-label use of abiraterone [in combination with prednisolone and androgen deprivation therapy] for the treatment of newly diagnosed low-risk metastatic hormone-sensitive prostate cancer, in line with

**PROTECTIVE MARKING: NONE**

<b>ITEM</b>	<b>SUBJECT</b>	<b>ACTION</b>
	NCMAG 110.	

**NCMAG 110 - Abiraterone acetate 500mg film-coated tablets is routinely available in line with national guidance (NCMAG 110).**

**Indication under review: [off-label use] in combination with prednisolone and androgen deprivation therapy for the treatment of newly diagnosed low-risk metastatic hormone-sensitive prostate cancer patients who are not suitable for currently accessible on-label alternatives.**

**This advice applies only in the context of the NHS Scotland national framework contract, delivering the cost-effectiveness results upon which the decision was based, or a national framework contract or list price that is equivalent or lower. The generic product available at the lowest acquisition cost should be prescribed. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.**

**FTEAM**

**8.4. SMC 2596 - VUTRISIRAN 25MG SOLUTION FOR INJECTION IN PREFILLED SYRINGE (AMVUTTRA®)**

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

The Group considered the request for vutrisiran for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adults with stage 1 or stage 2 polyneuropathy.

The Group noted that:

- hATTR amyloidosis is a rare metabolic disorder, with treatments initiated on the direction of specialists
- vutrisiran and patisiran, the alternative treatment option, are very expensive medicines
- patisiran is currently funded via the ultra-orphan financial risk share arrangements
- a financial assessment shows that introduction of vutrisiran has an immaterial cost difference across Scotland, but has significantly less service/homecare implications (3-monthly subcutaneous injection versus infusion every 3 weeks)
- personal communication with senior finance colleagues in NHS Grampian and National Services Scotland (NSS) confirmed that vutrisiran will be considered for inclusion in the Ultra-orphan medicines financial risk-share
- there is a local need for this product

The Group accepted the restricted local need for vutrisiran, as an alternative to patisiran, for the treatment of hATTR amyloidosis in adults with stage 1 or stage 2 polyneuropathy, as outlined in SMC 2596. Acceptance is subject to confirmation that vutrisiran is included in the NSS Ultra-orphan medicines financial risk-share arrangements.

**FD**

**Members deferred publication of the decision pending confirmation that vutrisiran is included in the NSS Ultra-orphan medicines financial risk-share arrangements.**

**9. PROVISIONAL ADVICE ISSUED**

**9.1. SMC PROVISIONAL ADVICE ISSUED OCTOBER 2023**

The Group noted the SMC provisional advice issued October 2023.

If the negative SMC recommendations and non-submission statement are published next month, these medicines will not be included on the formulary for the indications in question.

**9.2. NCMAG PROVISIONAL ADVICE ISSUED SEPTEMBER 2023**

The Group noted the NCMAG provisional advice issued September 2023.

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
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**10. SMC PUBLISHED ADVICE - OCTOBER 2023**

The Group noted the SMC advice published October 2023.

Following publication of the negative SMC recommendation for lutetium (<sup>177</sup>Lu) vipivotide tetraxetan (Pluvicto<sup>®</sup>)▼ SMC 2517, this medicine will not be included on the Grampian Joint Formulary for the indication in question.

**FTEAM**

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

- SMC 2599 atogepant (Aquipta<sup>®</sup>)▼ (submission expected)
- SMC 2587 belzutifan (Welireg<sup>®</sup>)▼
- SMC 2604 darolutamide (Nubeqa<sup>®</sup>)▼ (submission expected)
- SMC 2569 fenfluramine (Fintepla<sup>®</sup>)▼ (submission expected)
- SMC 2576 maribavir (Livtency<sup>®</sup>)▼ (submission expected)
- SMC 2518 olaparib (Lynparza<sup>®</sup>) (submission expected)
- SMC 2562 regorafenib (Stivarga<sup>®</sup>)
- SMC 2497 semaglutide (Wegovy<sup>®</sup>)
- SMC 2570 voclosporin (Lupkynis<sup>®</sup>)▼
- SMC 2600 zanubrutinib (Brukinsa<sup>®</sup>)▼ (submission received)

Local advice for these medicines and indications will be included in the October 2023 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'.

**FTEAM**

SMC 2548 - BREXUCABTAGENE AUTOLEUCEL 0.4 – 2 × 10<sup>8</sup> CELLS DISPERSION FOR INFUSION (TECARTUS<sup>®</sup>)

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

Ms Doney confirmed that:

- Tecartus<sup>®</sup> is:
  - included on the formulary for relapsed or refractory mantle cell lymphoma
  - Chimeric Antigen Receptors Cell Therapy (CAR-T). CAR-T is a highly complex treatment, it is a type of immunotherapy which involves collecting and using the patients' own immune cells to treat their condition.
  - an advanced therapy medicinal product (ATMP) that must be administered in a qualified treatment centre by a physician with experience in the treatment of haematological malignancies and trained for administration and management of patients treated with Tecartus. At least one dose of tocilizumab for use in the event of cytokine release syndrome (CRS) and emergency equipment must be available prior to infusion. The qualified treatment centre must have access to an additional dose of tocilizumab within 8 hours of each previous dose.
  - is currently only available from specialist centres. If a local need is identified, patients are discussed at a national multidisciplinary team (MDT) and if appropriate allotted treatment in a qualified treatment centre (which may be elsewhere in the UK).

The Group accepted that Tecartus<sup>®</sup> should be noted as non-formulary because treatment is currently only available from specialist centres.

**SMC 2548 - Brexucabtagene autoleucel 0.4 – 2 × 10<sup>8</sup> cells dispersion for infusion (Tecartus<sup>®</sup>) is routinely available from a specialist centre in another health board. Indication under review: treatment of adults 26 years of age and above with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL). In a single-arm, open-label, phase I/II study in patients with relapsed or refractory**

ITEM SUBJECT

ACTION

(R/R) ALL who received brexucabtagene autoleucel, overall complete remission rate was 71%.

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.

Not routinely available in NHS Grampian. If local need identified treatment is available from a specialist centre in another health board.

Tecartus® must be administered in a qualified treatment centre by a physician with experience in the treatment of haematological malignancies and trained for administration and management of patients treated with Tecartus®. At least 1 dose of tocilizumab for use in the event of cytokine release syndrome (CRS) and emergency equipment must be available prior to infusion. The qualified treatment centre must have access to an additional dose of tocilizumab within 8 hours of each previous dose. In the exceptional case where tocilizumab is not available due to a shortage that is listed in the MHRA Central Alerting System, suitable alternative measures to treat CRS instead of tocilizumab must be available prior to infusion.

FTEAM

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM - OCTOBER 2023

None.

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update September 2023), 12.2 (Grampian Area Drug and Therapeutics Committee (GADTC) minute July 2023), 12.3 and 12.4 (Grampian Primary Care Prescribing Group (PCPG) minute May and July 2023) were noted.

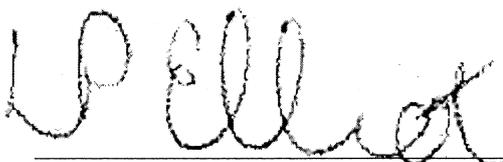
13. AOCB

None.

DATE OF NEXT MEETING

Tuesday 21 November 2023 starting at 14.30 via Microsoft Teams

CHAIR'S SIGNATURE



DATE 21 NOVEMBER 2023