

**NHS GRAMPIAN**  
**Minute of Formulary Group Meeting**  
**Tuesday 15 March 2022 at 14:30 via Microsoft Teams**

**PRESENT**

Ms L Cameron  
Ms A Davie  
Ms F Doney  
Dr L Elliot (Chair)  
Dr J Fitton  
Mrs G McKerron  
Dr M Metcalfe  
Mrs L Montgomery  
Mrs K Neave  
Mrs S O'Beirne  
Mr M Paterson  
Mr R Sivewright

**APOLOGIES**

Dr D Culligan  
Ms M Galvin  
Dr J Newmark

**APPROVED**

**IN ATTENDANCE**

Miss Julie Le Gourrierec, Rotational Pharmacist Aberdeen Royal Infirmary (ARI), observer  
Ms Christine Hay, Formulary and Medicines Management Pharmacist  
Mrs Anne Rembisz, Formulary Team administrator

<b>ITEM</b>	<b>SUBJECT</b>	<b>ACTION</b>
	The Chair welcomed members, opened the meeting and noted that a quorum was present.	
	The Chair welcomed Miss Julie Le Gourrierec, Rotational Pharmacist, to the meeting as an observer.	
<b>1.</b>	<b>APOLOGIES</b> Apologies for absence were requested and noted.	
<b>2.</b>	<b>DRAFT MINUTE OF THE MEETING HELD 15 FEBRUARY 2022</b> 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 approval.	<b>FD</b>
<b>3.</b>	<b>PRESENTATION</b> None.	
<b>4.</b>	<b>MATTERS ARISING</b>	
	<b>4.1. ACTION LOG</b> The action log was noted. No additional items were identified that should have been included on the agenda.	
	<b>4.2. SINGLE NATIONAL FORMULARY UPDATE</b> The Single National Formulary (SNF) has moved to a regional model approach, with the East Region Formulary being the test case. NHS Lothian is working with NHS Borders and NHS Fife in developing a new formulary website/platform. The formulary chapters are under review and as the sections are completed, a position will be reached where the new NHS Lothian formulary website will	

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	be re-branded as the 'East Region Formulary' and users will switch to using the new website.	
	Item closed.	FTEAM
	<p>PRE-ELECTION PERIOD</p> <p>The Chair reported that the pre-election period started yesterday (14 March 2022). Public bodies, such as the NHS, must remain neutral throughout this period while conducting their usual business. In practice, this means our buildings may not be used for election campaigning and staff should not participate in election activities while performing work duties.</p> <p>SMC advice will be published, and it will be business as usual for the Formulary Group with decisions and minutes published during the pre-election period.</p>	
5.	<b>FORMULARY GROUP DECISIONS FEBRUARY 2022 – PUBLISHED – 28/02/2022</b>	
	Members ratified the decisions of the February 2022 meeting as published.	FTEAM
6.	<b>NETFORMULARY/FORMULARY REVIEW</b>	
	Items 6.1 and 6.2 were taken together.	
	<b>6.1. ATALUREN (TRANSLARNA®)</b>	
	<b>6.2. VOLANESORSEN (WAYLIVRA®)</b>	
	Ms Doney reported that the formulary entries for ataluren (Translarna®) ▼ and volanesorsen (Waylivra®) ▼ have been updated on the formulary website.	
	<p>Ataluren for the treatment of Duchenne muscular dystrophy (DMD) resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 2 years and older using the ultra-orphan framework.</p> <p>February 2022, PTC Therapeutics Ltd has now met all the conditions of the pathway, including providing a data collection plan and a Patient Access Scheme (PAS). Ataluren will be available on the NHS in Scotland through National Services Division's (NSD's) Ultra-orphan Drugs Risk Sharing Scheme for up to three years while further evidence on its effectiveness is generated. The SMC will then review the available evidence after the three years and make a decision on its routine use in this patient group in NHS Scotland.</p>	
	<p>Volanesorsen (Waylivra®) ▼ as an adjunct to diet in adults with genetically confirmed familial chylomicronaemia syndrome (FCS) and at high risk for pancreatitis, in whom response to diet and triglyceride lowering therapy has been inadequate.</p> <p>November 2020, Akcea Therapeutics UK Ltd, met all the conditions of the pathway, including providing a data collection plan and a Patient Access Scheme (PAS). Volanesorsen is available on the NHS in Scotland through NSD's Ultra-orphan Drugs Risk Sharing Scheme (the inherited metabolic diseases (IMD) medicines risk share) for up to three years while further evidence on its effectiveness is generated. The SMC will then review the available evidence after the three years and make a decision on its routine use in this patient group in NHS Scotland.</p>	
	<b>6.3. SBAR - MEXILETINE CAPSULES</b>	
	There were no declarations of interest recorded in relation to this product.	
	The Group considered information regarding a newly licensed mexiletine hydrochloride capsule.	

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
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The Group noted:

- February 2022, a new licensed generic mexiletine hydrochloride capsule (50mg, 100mg and 200mg) was marketed
- the new product is licensed for the treatment of documented ventricular arrhythmias which, in the judgement of the physician, are considered as life-threatening
- Namuscla®:
  - was previously the only licensed mexiletine capsule
  - is licensed for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic disorders, and is currently non-formulary for its licensed indication (awaiting submission from the service)
  - is noted as a 167mg strength which refers to the mexiletine base, which is equivalent to 200mg mexiletine hydrochloride
  - costs significantly more than generic mexiletine hydrochloride
- mexiletine hydrochloride:
  - is already included on formulary for ventricular arrhythmias and there is a patient group established on mexiletine hydrochloride for this indication, and treatment will always be started by secondary care (cardiologists)
  - [for ventricular tachycardia] the unlicensed product is used because Namuscla® does not provide sufficient flexibility to allow dose adjustments
- the Medicines and Healthcare products Regulatory Agency (MHRA) advises that an unlicensed product should not be used where a product is available and licensed within the UK could be used to meet the patient's needs
- Medicines Information has reviewed the new product and advised that patients currently maintained on unlicensed mexiletine hydrochloride can be switched to the new licensed mexiletine hydrochloride preparation
- care should be taken to ensure the patient's current dose is based on the hydrochloride salt and not the dose as mexiletine base
- when using 200mg capsules Community Pharmacy colleagues may need to be aware of the indication in order to dispense the correct product, and branded prescribing could be considered [for Namuscla®]
- risk mitigation measures should be reviewed [by the relevant Pharmacy Leads]:
  - risk of confusions when prescribing, dispensing, or taking mexiletine
  - need to disseminate information for Community Pharmacists for dispensing as well as for practices and pharmacotherapy teams to ensure the correct product is selected
  - ScriptSwitch messaging could minimise the potential for prescribing/selection of the wrong preparation

The Group accepted that there is an established need for mexiletine hydrochloride capsules, as licensed for the treatment of ventricular arrhythmias.

The Formulary Group supported substituting licensed mexiletine hydrochloride hard capsules for the unlicensed mexiletine hydrochloride preparation.

Acceptance is subject to consideration of and implementation of additional risk management measures to ensure the correct preparation is selected when prescribing and dispensing mexiletine hydrochloride.

**PHARMACY  
LEADS**

**SBAR - Mexiletine hydrochloride 50mg, 100mg, 200mg hard capsules is routinely available in line with local guidance.**

**Indication under review: for the treatment of documented ventricular arrhythmias which, in the judgement of the physician, are considered as life-threatening.**

**It was classified 1b- available for restricted use under specialist supervision and 8c - treatment to be initiated in hospital prior to handover. Treatment with mexiletine should be initiated and monitored by a specialist experienced in the treatment of cardiac arrhythmias. The optimal dosage should be determined individually based on the patient's response and tolerance.**

**FTEAM**

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
7.	<b>OTHER BUSINESS</b>	
7.1.	<b>DECLARATION OF INTEREST REGISTER 2021</b>	
<p>The Chair confirmed that members' had confirmed their conflicts of interests for 2021, and the Group's Register of Interests [for 2021] will be published on the Formulary Group intranet site by the end of March.</p>		FTEAM
7.2.	<b>SMC STRATEGY 2020 - 2023</b>	
<p>Members noted the content of the Scottish Medicines Consortium Strategy 2020-2023 November 2021.</p>		
7.3.	<b>EXPLORATORY WORK OF THERAPEUTICS FOR PEOPLE WITH COVID-19 [ID4038]</b>	
<p>Ms Doney reported that NICE, with support from SMC and other bodies, plans to appraise the clinical- and cost effectiveness of remdesivir, tocilizumab, casirivimab and imdevimab, baricitinib, sotrovimab, molnupiravir, anakinra, lenzilumab and PF-07321332 and ritonavir within their proposed marketing authorisations for treating people with coronavirus disease 2019 (COVID-19).</p>		
<p>The advice will most likely be published as a NICE Multiple Technology Appraisal (MTA) and the outcome will be presented to members when it is available.</p>		
7.4.	<b>SAPROPTERIN</b>	
<p>Ms Doney reported that the Area Drug and Therapeutics Committee Collaborative (ADTC Collaborative), supported by Health Boards, is consulting on the proposal to issue a statement that will support access to sapropterin thereby removing the need to consider individual patient treatment requests at a local level.</p>		
<p>Sapropterin is an expensive medicine, the originator product Kuvan® is subject to 'not recommended' advice from the SMC. A generic product has now been launched and SMC advice will not be available as generics are outwith remit for SMC.</p>		
<p>The ADTC Collaborative proposal is under discussion and may inform future policy work around revision of Scottish Government CEL 17 (2010). Feedback will be provided when available.</p>		FD
8.	<b>NEW PRODUCT REQUESTS</b>	
8.1.	<b>FG1SMC 2382 - OSIMERTINIB (NON-SMALL CELL LUNG CANCER (FIRST LINE))</b>	
<p>Dr Fitton and Mr Paterson declared personal, non-specific interests in AstraZeneca UK Limited, and took part in decision-making.</p>		
<p>The Group considered the request for osimertinib as monotherapy for the first-line treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations.</p>		
<p>The Group noted:</p>		
<ul style="list-style-type: none"><li>• osimertinib:<ul style="list-style-type: none"><li>▪ is a third generation tyrosine kinase inhibitor (TKI)</li><li>▪ is already included on formulary for the treatment of adults with locally advanced or metastatic EGFR T790M mutation positive NSCLC in patients who have received previous treatment with an EGFR TKI</li><li>▪ is given as an oral tablet daily until disease progression or unacceptable toxicity</li><li>▪ had a median progression free survival in the FLAURA study of 18.9 months [versus 10.2 months for first-generation agents erlotinib or gefitinib]</li><li>▪ was accepted for use in NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers</li></ul></li></ul>		

**PROTECTIVE MARKING: NONE**

<b>ITEM</b>	<b>SUBJECT</b>	<b>ACTION</b>
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- the FLAURA study only included patients with Ex19del or L858R EGFR mutations, however the licensing does not restrict treatment to these specific EGFR mutations so the service plans to use it in patients with any EGFR mutations
- patient numbers are expected to be small
- a degree of cost offset is available as osimertinib will replace older generation TKIs
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of osimertinib, and the PAS is a complex PAS
- there is limited head-to-head data comparing the different generations of targeted agents
- [in NSCLC] there is an issue of acquired resistance with the first- and second-generation TKIs

Members discussed the data available for the different generations of targeted agents and the difficulty this poses [in terms of clinical- and cost-effectiveness] as new expensive agents with marginal benefits come to market and there are no or limited direct comparative data.

Members requested clarity about the proposed treatment pathway particularly as the market becomes more crowded with new agents and generic medicines. A lung cancer specialist will be invited to discuss the treatment pathway(s) and data including genetics/sequencing, as in this case the trial data was limited to patients with Ex19del or L858R EGFR mutations, however osimertinib will be used in patients with any EGFR mutation.

**FTEAM**

The Group accepted the restricted local need for osimertinib as monotherapy for the first-line treatment of adults with locally advanced or metastatic NSCLC with activating EGFR mutations as outlined in SMC 2382.

**SMC 2382 - Osimertinib 40mg, 80mg film-coated tablets (Tagrisso®) ▼ is routinely available in line with national guidance (SMC 2382).**

**Indication under review: as monotherapy for the first-line treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations.**

**Osimertinib, compared with two other EGFR tyrosine kinase inhibitors, improved progression-free survival in adults with locally advanced or metastatic NSCLC with activating EGFR mutations.**

**This advice takes account of the views from a Patients and Clinician Engagement (PACE) meeting.**

**This advice applies only in the context of an approved NHS Scotland Patients 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 with osimertinib should be initiated by a physician experienced in the use of anti-cancer therapies. When considering the use of osimertinib, EGFR mutation status (in tumour or plasma specimens for locally advanced or metastatic setting) should be determined using a validated test method.**

**FTEAM**

## **8.2. FG1SMC 2383 - OSIMERTINIB (NSCLC (ADJUVANT TREATMENT))**

Dr Fitton and Mr Paterson declared personal, non-specific interests in AstraZeneca UK Limited, and took part in decision-making.

The Group considered the request for osimertinib as monotherapy for the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIa NSCLC whose tumours have EGFR exon 19 deletions (Ex19del) or exon 21 (L858R) substitution mutations.

## PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<p>The Group noted:</p> <ul style="list-style-type: none"><li>osimertinib<ul style="list-style-type: none"><li>[for this indication] SMC has included a three year clinical stopping rule</li><li>is the first TKI licensed as an adjuvant treatment for resected EGFR positive NSCLC</li><li>is given as an oral tablet daily until disease progression or unacceptable toxicity</li><li>was accepted for restricted use in NHS Scotland following the output from the PACE process</li></ul></li><li>a validated test should be performed using tumour tissue DNA from biopsy or surgical specimen to check EGFR mutation positive status</li><li>the median duration of treatment exposure in the ADAURA study was 22.5 months</li><li>patient numbers are expected to be very small</li><li>minimal cost offset may be available</li><li>the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of osimertinib</li></ul> <p>The Group accepted the restricted local need for osimertinib as monotherapy for the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIa NSCLC whose tumours have EGFR Ex19del or exon 21 (L858R) substitution mutations as outlined in SMC 2383.</p> <p><b>SMC 2383 - Osimertinib 40mg, 80mg film-coated tablets (Tagrisso®) ▼ is routinely available in line with national guidance (SMC 2383).</b></p> <p><b>Indication under review: as monotherapy for the adjuvant treatment after complete tumour resection in adults with stage IB-IIIa non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions (Ex19del) or exon 21 (L858R) substitution mutations.</b></p> <p><b>Restriction: treatment with osimertinib is subject to a three-year clinical stopping rule.</b></p> <p><b>In a placebo-controlled phase III study, osimertinib significantly improved disease free survival (DFS) in patients with completely resected EGFR mutation-positive NSCLC.</b></p> <p><b>This advice takes account of the views from a Patients and Clinician Engagement (PACE) meeting.</b></p> <p><b>This advice applies only in the context of an approved NHS Scotland Patients 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.</b></p> <p><b>It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment with osimertinib should be initiated by a physician experienced in the use of anti-cancer therapies. When considering the use of osimertinib, EGFR mutation status (in tumour specimens for adjuvant treatment) should be determined using a validated test method.</b></p>	

FTEAM

### 8.3. FG1SMC 2360 - GUSELKUMAB (PSORIATIC ARTHRITIS)

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

The Group considered the request for guselkumab alone or in combination with methotrexate (MTX) for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.

The Group noted:

- guselkumab
  - blocks the activity of Interleukin 23 (IL-23)
  - is included on formulary for the treatment of moderate to severe plaque psoriasis
  - [for this indication] is currently recorded as non-formulary, 'not routinely available'

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	<p>as there is local preference for alternative medicines' as the service stated that the IL-23 inhibitors seem to be more effective for skin disease than the associated arthritis. However, the Service has revised its position as there are data to suggest that the more targeted anti-IL-23 inhibitors are more effective than those that inhibit IL-23 and IL-12 (ustekinumab) and there is evidence to suggest that guselkumab is comparable to IL-17 inhibitors or anti-tumour necrosis factor inhibitors for arthritis.</p> <ul style="list-style-type: none"><li>▪ is a subcutaneous injection designed for self-administration after training</li><li>• the company asked SMC to restrict guselkumab treatment to three groups:<ul style="list-style-type: none"><li>▪ patients whose disease has not responded adequately or who have been intolerant to two previous conventional DMARD therapies but have not received biologic DMARD therapy (biologic-naïve population);</li><li>▪ patients whose disease has not responded adequately to conventional DMARDs and one or more tumour necrosis factor inhibitors (biologic-experienced population);</li><li>▪ patients in whom tumour necrosis factor inhibitors are contraindicated or not tolerated.</li></ul></li><li>• patient numbers are expected to be small</li><li>• treatment may be long-term so costs will be cumulative</li><li>• cost offset is available as guselkumab will be used as a second- or third-line agent in place of another biologic</li><li>• the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of guselkumab</li></ul> <p>The Group accepted the restricted local need for guselkumab alone or in combination with MTX for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy as outlined in SMC 2360.</p> <p><b>SMC 2360 - Guselkumab 100mg solution for injection in pre-filled pen (Tremfya®) ▼ is routinely available in line with national guidance (SMC 2360).</b></p> <p><b>Indication under review: alone or in combination with methotrexate (MTX) for the treatment of active psoriatic arthritis in adults:</b></p> <ul style="list-style-type: none"><li>• (i) whose disease has not responded adequately or who have been intolerant to two previous conventional disease-modifying antirheumatic drug (DMARD) therapies but have not received biologic DMARD therapy (biologic-naïve population)</li><li>• (ii) whose disease has not responded adequately to conventional DMARDs and one or more tumour necrosis factor (TNF) inhibitors (biologic-experienced population)</li><li>• (iii) in whom TNF inhibitors are contraindicated or not tolerated.</li></ul> <p>Three phase III studies demonstrated superiority of guselkumab when compared with placebo in reducing signs and symptoms of psoriatic arthritis in patients who had not previously received a TNF inhibitor medication and in those with an inadequate response or intolerance to TNF inhibitors.</p> <p>This advice applies only in the context of an approved NHS Scotland Patients 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.</p> <p>It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Guselkumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which guselkumab is indicated.</p>	

FTEAM

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
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**8.4. FG1 439/21 - DAPSONE (MULTIPLE DERMATOLOGICAL INDICATIONS)**

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

The Group considered the request for dapsones for the treatment of multiple dermatological indications:

- dermatitis herpetiformis and other dermatoses
- and
- [off-label] urticaria, immunobullous disease, hidradenitis suppurativa, vasculitis, aphthous ulceration, pyoderma gangrenosum, sweets syndrome and other neutrophilic dermatoses

The Group noted:

- dapsones:
  - is a sulphonamide antibiotic and acts as an anti-inflammatory drug
  - is only licensed for the treatment of dermatitis herpetiformis and other dermatoses [for adults and children over 12 years]
  - used for urticaria, immunobullous disease, hidradenitis suppurativa, vasculitis, aphthous ulceration, pyoderma gangrenosum, sweets syndrome and other neutrophilic dermatoses would be off-label use
  - dosing is variable dependent upon indication
  - is currently prescribed and supplied by the Dermatology Service with some prescribing in Primary Care. The Service wishes to transfer all prescribing to Primary Care and has provided a draft shared care arrangement to facilitate this.
- the Antimicrobial Management Team (AMT) discussed the use of dapsones for the specified indications, and supported the formulary request as there was no change in prescribing practice or an increase in patient numbers expected
- other Health Boards have included dapsones on their formularies:
  - in Greater Glasgow and Clyde dapsones is included restricted to specialist initiation for the licensed indications only
  - in Tayside, there is a shared care agreement in place for the use of dapsones in skin conditions, including dermatitis herpetiformis, autoimmune bullous disorders, neutrophilic vasculitides, hidradenitis suppurativa, acne conglobate, delayed pressure urticaria and pyoderma gangrenosum
- dapsones is included as a treatment option in the British Association of Dermatologists (BAD) guidelines for chronic urticaria, hidradenitis suppurativa and bullous pemphigoid and mentioned in the BAD patient information leaflets for dermatitis herpetiformis, linear IgA disease, pemphigoid, hidradenitis suppurativa, cutaneous vasculitis, pyoderma gangrenosum and sweet's syndrome
- the Service estimates it currently starts dapsones in a small number of patients, and does not expect this to increase over time
- dapsones is available as 50mg and 100mg tablets, and the 50mg tablet costs less per milligram than the 100mg tablet [circa. half the cost]. The 50mg is the only strength included on the Scottish Drug Tariff (SDT). The Service has no concerns if only dapsones 50mg tablets are included on formulary.
- for the off-label indications treatment would be limited to where standard treatments are ineffective

Members discussed the requested indications and proposal to transfer prescribing and monitoring to Primary Care. The small patient numbers and lack of robust evidence to support all of the indications requested raised questions. With the small numbers, there was a concern about how familiar General Practice would become with the drug, particularly for its off-label indications. Members felt that prescribing remaining within the managed sector with monitoring via the monitoring hubs would be a more appropriate pathway for patients.

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	<p>Members supported formulary inclusion of dapsone for its licensed indication, and limiting the formulary preparation to the 50mg tablet. If patients require treatment for an off-label indication this will still be available as an individual patient request.</p> <p>The Group accepted the restricted local need for dapsone as licensed for the treatment of dermatitis herpetiformis and other dermatoses. Due to the expected small patient numbers prescribing will remain within the managed service with the monitoring hubs available for the required monitoring.</p> <p><b>FG1 439/21 - Dapsone 50mg tablets is routinely available in line with local guidance.</b> <b>Indication under review: for the treatment of adults and adolescents over 12 years with dermatitis herpetiformis and other dermatoses.</b> <b>It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.</b></p>	
	<p><b>8.5. FG1SMC 2394 - NIVOLUMAB (COLORECTAL CANCER)</b></p> <p>There were no declarations of interest recorded in relation to this product.</p> <p>Ms Hay confirmed that currently there is not a local need for nivolumab [in combination with ipilimumab] for the treatment of adults with mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer after prior fluoropyrimidine-based combination chemotherapy on the formulary.</p> <p>The Oncology Service does not wish to include this combination on formulary at this time because all patients with dMMR/MSI-H metastatic colorectal cancer will have had first-line pembrolizumab, so any chemotherapy will be second-line and it is unclear from the literature if re-challenge with immunotherapy after failure in the first-line setting is successful.</p> <p>The Group accepted the Oncology Service's position that nivolumab, for this indication, would not be included on the formulary at this time.</p> <p><b>SMC 2394 - Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) is not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time.</b> <b>Indication under review: in combination with ipilimumab for the treatment of adult patients with mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer after prior fluoropyrimidine-based combination chemotherapy.</b> <b>In a single-arm cohort of a phase II study, nivolumab in combination with ipilimumab was associated with clinically relevant overall response rates in adults with dMMR or MSI-H metastatic colorectal cancer who had received prior fluoropyrimidine-based chemotherapy.</b> <b>This advice applies only in the context of an approved NHS Scotland Patients 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.</b> <b>Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time.</b></p>	<p>FTEAM</p> <p>FTEAM</p>
<b>9.</b>	<p><b>SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED MARCH 2022</b></p> <p>The Group noted the SMC provisional advice issued March 2022.</p> <p>If the non-submission statements are published next month, these medicines will not be included on the formulary for the indications in question.</p>	<p>FTEAM</p>

**PROTECTIVE MARKING: NONE**

**ITEM SUBJECT**

**ACTION**

**10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED MARCH 2022**

The Group noted the SMC advice published March 2022.

Following publication of the negative SMC recommendations, for solriamfetol (Sunosi®) ▼ SMC 2419 and hydrocortisone modified-release hard capsules (Efmody®) SMC 2414, and the non-submission statements, for blinatumomab (Blinicyto®) ▼ SMC 2468, daratumumab (Darzalex®) ▼ SMC 2469, givosiran (Givlaari®) ▼ SMC 2470 and standardised allergen extract of pollen from white birch betula verrucosa (Itulazax 12 SQ-Bet®) ▼ SMC 2471, these medicines will not be included on the Grampian Joint Formulary for the indications in question.

**FTEAM**

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

- SMC 2446 sacituzumab govitecan (Trodelvy®) ▼ (submission expected)
- SMC 2443 sotorasib (Lumykras®) ▼ (submission expected)
- SMC 2405 berotralstat (Orladeyo®) ▼ (submission received)
- SMC 2404 dostarlimab (Jemperli®) ▼ (submission expected)
- SMC 2415 lorlatinib (Lorviqua®) ▼ (submission expected)

Local advice for these medicines and indications will be included in the March 2022 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'.

**FTEAM**

**11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM - MARCH 2022**

None.

**12. DOCUMENTS FOR INFORMATION**

Items 12.1 (Drug Safety Update February 2022), 12.2 (Antimicrobial Management Team minute September 2021) and 12.3 (Antimicrobial Management Team minute November 2021) were noted.

**13. AOCB**

**NOMINATIONS FOR VICE-CHAIR**

In the past, the Group has had one or two vice-chairs. For resiliency and succession planning, the Chair asked for members interested in becoming a vice-chair to message Ms Doney. Nominations will be discussed at the Formulary Group meeting in April.

**ALL**

**THANK YOU**

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

**DATE OF NEXT MEETING**

Tuesday 19 April 2022 starting at 14.30 via Microsoft Teams

**CHAIR'S SIGNATURE**



**DATE 19 APRIL 2022**