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

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Ms L Cameron	
Ms F Doney		
Dr L Elliot (Chair)		
Dr J Fitton (from Item 4.1)		
Ms M Galvin		
Mrs G McKerron		
Dr M Metcalfe		
Mrs L Montgomery		
Mrs K Neave		
Dr J Newmark (from Item 4.1)		
Mrs S O'Beirne		
Mr M Paterson		
Mr R Sivewright (from Item 4.3)		

IN ATTENDANCE

Ms Christine Hay, Formulary and Medicines Management Pharmacist
Mrs Anne Rembisz, Formulary Team administrator

ITEM	SUBJECT	ACTION
	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 18 JANUARY 2022**	
	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.	FD
3.	**PRESENTATION**	
	None	
4.	**MATTERS ARISING**	
4.1.	**ACTION LOG**	
	The action log was noted. No additional items were identified that should have been included on the agenda.	
4.2.	**NINTEDANIB STOPPING RULES**	
	At the November 2021 meeting, members requested clarification if there was a plan to implement stopping rules for nintedanib, as Ofev®, for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with progressive phenotype (other than idiopathic pulmonary fibrosis).	
	Ms Doney confirmed that a sustained decline in lung function, FVC (forced vital capacity) reduced by over 10% in the absence of any other reversible causes would be the criteria the Respiratory Team will use.	

ITEM	SUBJECT	ACTION

4.3. NHS ENGLAND STATIN INTOLERANCE PATHWAY (UPDATE)

Ms Doney confirmed that:
- the relevant authority in NHS England has confirmed that NHS Grampian may adopt or adapt their published Statin Intolerance Pathway
- changing the pathway to reference SMC guidance rather than NICE technology appraisals will lose the "NICE Endorsement" tag
- the pathway will be taken to the Grampian Area Drug and Therapeutics Committee (GADTC) for approval of local adoption with a notation that the relevant advice would be SMC advice **FD**

5. FORMULARY GROUP DECISIONS JANUARY 2022 – PUBLISHED 01/02/2022

5.1. FORMULARY GROUP DECISIONS JANUARY 2022

Members ratified the decisions of the January 2022 meeting as published. **FTEAM**

6. NETFORMULARY/FORMULARY REVIEW

6.1. ADRENALINE TARTRATE (EMERADE®) (ADRENALINE AUTO-INJECTOR)

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

The Group considered the information provided regarding the re-supply of the adrenaline auto-injector Emerade® to the UK market.

The Group noted:
- Emerade®:
  - was previously included on the formulary, but due to a problem with the device it was withdrawn from the market in 2020
  - [as the 300microgram and 500microgram strengths] is being re-supplied to the market [the 150microgram strength will not be returning to market at this time, further details of re-supply will be provided at a later date]
  - has a different mechanism type to the other adrenaline auto-injectors; a triple spring mechanism compared to the cartridge mechanisms of Epipen® and Jext®
  - is the only adrenaline auto-injector that is available in a 500microgram strength, and this strength is not recommended for use in children
  - is rarely prescribed locally, but inclusion on the formulary as a second-line option, is warranted in some circumstances such as body size or patients moving into NHS Grampian that are already established on Emerade®
- the labelled strength of adrenaline auto-injectors reflects the dose of adrenaline dispensed by the device in a single injection, however, the amount of adrenaline reaching the bloodstream in a particular time window can differ according to patient-specific and device-specific factors
- Emerade® is the device that people [staff and patients/carers] are least familiar with
- the adrenaline auto-injectors have device-specific training requirements and the Resus Nurses will be contacted to update the relevant training **FTEAM**

The Group accepted the restricted local need for Emerade® as a second-line option for the emergency treatment of severe acute allergic reactions.
Ms Doney will liaise with Dr Herriot to update the formulary entry to include situations where Emerade® would be considered appropriate for prescribing. **FD**

Adrenaline tartrate 300micrograms, 500micrograms solution for injection in pre-filled pen (Emerade®) is routinely available in line with local guidance.
Indication under review: for the emergency treatment of severe acute allergic reactions (anaphylaxis) triggered by allergens in foods, medicines, insect stings or bites, and other allergens as well as for exercise-induced or idiopathic anaphylaxis.

ITEM	SUBJECT	ACTION
	Restriction: as a second-line choice. **It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.**	**FTEAM**

6.2. *H. PYLORI* TREATMENT UPDATE (SECOND-LINE TREATMENT REGIMEN)

Ms Doney reported that for maximum effectiveness the local second-line *H. Pylori* treatment regimen [omeprazole + bismuth + metronidazole + tetracycline] has increased from 7 to 14 days.
The change is based on expert advice from the Gastroenterology Service and is supported by the Antimicrobial Management Team (AMT).
The formulary entry has been updated.

7. OTHER BUSINESS

None

8. NEW PRODUCT REQUESTS

8.1. FG1 SMC 2370 - SELPERCATINIB (THYROID CANCER)

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

The Group considered the request for selpercatinib monotherapy for the treatment of thyroid cancer as outlined in SMC 2370.

The Group noted:

- selpercatinib monotherapy was accepted by the SMC for two indications
  1) for adults with advanced RET fusion-positive thyroid cancer who require systemic therapy following prior treatment with sorafenib and/or lenvatinib,
  2) for adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) who require systemic therapy following prior treatment with cabozantinib and/or vandetanib
- selpercatinib
  - [for these indications] was accepted by the SMC for use on an interim basis subject to ongoing evaluation and future assessment and has a conditional marketing authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA)
  - [for these indications] meets SMC orphan equivalent and end of life criteria, and was accepted for use within NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers
  - is an oral capsule taken twice a day until disease progression or unacceptable toxicity, and dosing is based on body weight
- licensing and SMC acceptance for selpercatinib in advanced RET-mutant MTC is following prior treatment with cabozantinib and/or vandetanib, however neither of these agents are accepted by SMC for use in NHS Scotland for this indication
- the service confirmed that patients with advanced RET-mutant MTC would receive cabozantinib or vandetanib [via individual patient requests], however they would not receive both agents as there is no evidence to support sequential treatment
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of selpercatinib, and the PAS is a complex PAS
- patient numbers are expected to be very small
- the median duration of treatment with selpercatinib in LIBRETTO-001 was 12.9 months in RET-fusion positive patients and 12.0 months in RET-mutant MTC patients
- selpercatinib represents a new cost as there are currently no second-line treatment options for this patient group

ITEM	SUBJECT	ACTION

The Group accepted the restricted local need for selpercatinib as monotherapy as outlined in SMC 2370 for the treatment of 1) adults with advanced RET fusion-positive thyroid cancer who require systemic therapy following prior treatment with sorafenib and/or lenvatinib, 2) adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) who require systemic therapy following prior treatment with cabozantinib and/or vandetanib.

SMC 2370 - Selpercatinib 40mg, 80mg hard capsules (Retsevmo®) ▼ is routinely available in line with national guidance, on an interim basis subject to ongoing evaluation and future reassessment (SMC 2370).
Indication under review: as monotherapy for the treatment of:
- **adults with advanced RET fusion-positive thyroid cancer who require systemic therapy following prior treatment with sorafenib and/or lenvatinib**
- **adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) who require systemic therapy following prior treatment with cabozantinib and/or vandetanib**

In a phase I/II study, in previously treated patients with RET-fusion positive thyroid cancer or RET-mutant MTC, selpercatinib was associated with an objective response rate of 79% and 69% respectively.
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. Selpercatinib should be initiated and supervised by physicians experienced in the use of anticancer therapies. FTEAM

8.2. FG1 SMC 2387 - IBRUTINIB (WALDENSTRÖM'S MACROGLOBULINAEMIA (WM))

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

The Group considered the request for ibrutinib monotherapy for the treatment of adults with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy.

The Group noted:
- ibrutinib:
  - is an oral treatment that is taken once daily
  - is already included on formulary for use in combination with rituximab [SMC 2259] for the same patient group
  - [for this indication] meets SMC orphan criteria, and was accepted for restricted use within NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers
- the Service wishes to have both monotherapy and combination therapy included on the formulary as there are no high quality comparative data to indicate that the addition of rituximab is clinically superior. In general, practice for B-cell lymphomas is that combination with rituximab improves outcomes. However, there are patient factors that may be relevant when considering monotherapy, e.g. ability or willingness to travel, and the perceived risk of COVID with rituximab.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ibrutinib, and the PAS is a complex PAS
- patient numbers are expected to be very small
- the median duration of treatment was not reported at final analysis but the median progression-free survival (PFS) is >5 years
- the service expects treatment duration to be similar for ibrutinib monotherapy or when used in combination with rituximab

ITEM	SUBJECT	ACTION

The Group accepted the restricted local need for ibrutinib monotherapy for the treatment of adults with WM who have received at least one prior therapy, as outlined in SMC 2387.

SMC 2387 - Ibrutinib 140mg, 280mg, 420mg film-coated tablets (Imbruvica®) is routinely available in line with national guidance (SMC 2387).
Indication under review: as a single agent for the treatment of adults with Waldenström's macroglobulinaemia who have received at least one prior therapy.
In a phase II study, in previously treated patients with Waldenström's macroglobulinaemia, ibrutinib was associated with an overall response rate of 87% to 90%.
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 this medicinal product should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. **FTEAM**

8.3. FG1 SMC 2395 - TIRBANIBULIN (ACTINIC KERATOSIS)

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

The Group considered the request for tirbanibulin for field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.

The Group noted:

- tirbanibulin:
  - is an ointment applied in a thin layer to the affected field (up to 25cm^2) once daily for one treatment cycle of five consecutive days, and the therapeutic effect should be assessed approximately 8 weeks after treatment starts
  - will become a first-choice option for thin, non-hyperkeratotic actinic keratosis as an alternative to diclofenac 3% gel (Solaraze®), fluorouracil 5% cream (Efudix®) and imiquimod 5% cream (Aldara®)
  - has a short treatment duration but a smaller treatment area when compared to the other treatment options
- there are no clinical data on more than one treatment course for the same area, so if recurrence occurs, or new lesions develop within the treatment area, other treatment options should be considered
- the Dermatology Service considers that tirbanibulin could be prescribed by Primary Care colleagues using the Primary Care Dermatology Society (PCDS) guidance that is linked to the NHS Scotland Dermatology patient pathway for Actinic Keratoses and Bowen's Disease

Members discussed the request and accepted that GPs currently follow the dermatology pathways. Mindful of dermatology waiting times members considered that tirbanibulin would be a safe and effective treatment option that GPs could prescribe for small, thin areas of non-hyperkeratotic actinic keratosis.

The Group accepted the restricted local need for tirbanibulin for field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults as outlined in SMC 2395.

ITEM	SUBJECT	ACTION
	SMC 2395 - Tirbanibulin 10mg/g ointment (Klisyri®) ▼ is routinely available in line with national guidance (SMC 2395). **Indication under review: field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.** **In two phase III studies, a greater proportion of adults with actinic keratosis affecting an area of 25cm^2 on the face or scalp achieved complete clearance when treated with tirbanibulin ointment 1% compared with vehicle.** **It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.**	**FTEAM**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED FEBRUARY 2022

The Group noted the SMC provisional advice issued February 2022.

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

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED FEBRUARY 2022

The Group noted the SMC advice published February 2022.

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

- SMC 2385 nivolumab (Opdivo®)
- SMC 2402 cannabidiol (Epidyolex®)
- SMC 2399 pemigatinib (Pemazyre®) ▼
- SMC 2400 enzalutamide (Xtandi®)
- SMC 2401 risdiplam (Evrysdi®) ▼
- SMC 2408 cenobamate (Ontozry®) ▼

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

SMC 2444 - DIROXIMEL FUMARATE (VUMERITY®) (RELAPSING REMITTING MULTIPLE SCLEROSIS)

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

The Group discussed the SMC advice for diroximel fumarate for the treatment of adults with relapsing remitting multiple sclerosis.

Ms Doney reported that:

- at this time, the specialist service does not wish to include diroximel fumarate on the formulary
- there are no comparative data between diroximel fumarate and dimethyl fumarate, and the Service believes diroximel fumarate may have similar efficacy to dimethyl fumarate with a slightly different side-effect profile

The Group supported the Service's position that diroximel fumarate would not be included on the formulary as there is a local preference for alternative medicines.

SMC 2444 - Diroximel fumarate 231mg gastro-resistant hard capsules (Vumerity®) is not routinely available as there is a local preference for alternative medicines.
Indication under review: treatment of adult patients with relapsing remitting multiple sclerosis.
Diroximel fumarate provides an additional treatment choice in the therapeutic class

ITEM	SUBJECT	ACTION
	of nuclear factor (erythroid-derived 2)-like 2 (Nrf2) activators. 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. Not routinely available as there is a local preference for alternative medicines.	**FTEAM**

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM – FEBRUARY 2022

Nil of note

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update January 2022), 12.2 (Medicine Guidelines and Policies Group minute August 2021) and 12.3 (Grampian Primary Care Prescribing Group minute October 2021) were noted.

13. AOCB

THANK YOU

Ms Doney confirmed that this might be Ms Hay's last meeting for a while as she will be starting maternity leave within the next six weeks. Ms Doney thanked Ms Hay for all of the work she has done preparing and presenting the reviews, her absence will be felt by the Formulary Team.

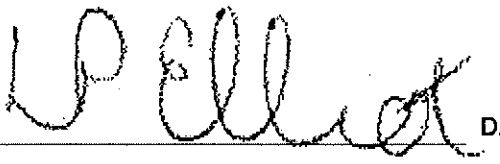
PROFESSOR JAMES MCLAY AWARD

Following the shocking news of the untimely passing of Professor James McLay members took time to acknowledge the enormous contribution that he has made to teaching, clinical practice and medicines management in Grampian and nationally. He was a charismatic physician who will be greatly missed.

A James McLay student prize and/or a student hardship fund for the Physician Associate/Clinical Pharmacology students will be established. Anyone wishing to donate can do so using the JustGiving page, https://www.justgiving.com/fundraising/jamesmclay.

DATE OF NEXT MEETING

Tuesday 15 March 2022 starting at 14.30 via Microsoft Teams

CHAIR'S SIGNATURE  **DATE 15 MARCH 2022**