NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 19 April 2022 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms L Cameron (from Item 8.3)	Ms A Davie	
Dr D Culligan	Mrs G McKerron	
Ms F Doney	Mrs K Neave	
Dr L Elliot (Chair)	Mr M Paterson	
Dr J Fitton		
Ms M Galvin		
Dr M Metcalfe		
Mrs L Montgomery		
Dr J Newmark		
Mrs S O'Beirne		
Mr R Sivewright		

IN ATTENDANCE
Mrs Anne Rembisz, Formulary Team administrator

Note due to technical difficulties some items were deferred to the May meeting.

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 15 MARCH 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, including items closed in the last month. No additional items were identified that should have been included on the agenda.	**FTEAM**
4.2.	**PENTOSAN**	
	Pentosan, as the brand Elmiron®, was discussed last year for a rare condition - the treatment of bladder pain syndrome characterised by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition. All patients should have an ophthalmologic examination after 6 months of use [for early detection of pigmentary maculopathy] and if there are no pathologic findings, regularly after 5 years of use.	
	Ms Doney proposed closing this item on the action log and progressing via the pharmacy and clinical leads to confirm the communication process with Primary Care to clarify that	

ITEM	SUBJECT	ACTION

the patient has attended for the relevant eye examinations and that treatment can be continued.

Members supported the proposal to progress this item through the clinical leads.
Item closed. **FTEAM**

4.3. NOMINATIONS FOR VICE-CHAIR

The Chair confirmed that to provide additional capacity nominations for two vice-chairs would be considered.

Ms Doney proposed Dr Metcalfe as Vice-Chair, Mrs Montgomery seconded. Motion carried. Dr Metcalfe accepted.
Dr Elliot proposed Ms Doney as a second Vice-Chair, Dr Metcalfe seconded. Motion carried. Ms Doney accepted.

4.4. DAPSONE (FEEDBACK FROM THE SERVICE)

Ms Doney confirmed that Dr McNeil, Consultant Dermatologist and Clinical Lead for Dermatology, has submitted an SBAR highlighting the service's concerns regarding the Group's recommendation that dapsone be prescribed and monitored solely within secondary care.

Dr McNeil will attend the May meeting to discuss the concerns with the Group.

5. FORMULARY GROUP DECISIONS MARCH 2022 – PUBLISHED – 28/03/2022

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

6. netFORMULARY/FORMULARY REVIEW

6.1. CMO REPORT 2021/2022 AND 93-DAY REPORT 2021/2022

Ms Doney highlighted the content of the CMO Report and the 93-Day Report for 2021/2022.

The NHS Grampian Formulary Group audit standard for the criteria below is 90%. For the time period April 2021 to March 2022 the relevant deadlines/audit standards have been met:

- CMO report [72 SMC accepted medicines]:
  - [the Group] reached a decision on a SMC accepted medicine within 90 days of the issue of SMC advice to NHS Boards (i.e. the advice is confidential for the first 30 days) (100%; 72/72)
  - the formulary decision was published on the Board website within 14 days of the decision being reached (100%; 72/72; 4/72 published at 14 days)
- 93-day report – timelines met for all decisions (243/244), 1 decision remains in draft but is still within its 93-day publication timeline [dapsone decision discussed under matters arising]

These reports will form part of the Group's annual report.

6.2. DISCONTINUATIONS/FORMULATION CHANGES

The Group reviewed the document highlighting discontinued medicines or those subject to formulation changes.

The Group supported the changes proposed by the Formulary Team:

- no action required for Triapin® 5mg/5mg modified-release tablets (felodipine/ramipril) as this is a non-formulary medicine that is not included on the formulary website

ITEM	SUBJECT	ACTION
	• the current website entries for bambuterol 10mg tablets (Bambec®) and tipranavir 250mg soft capsules and 100mg/mL oral solution (Aptivus®), non-formulary medicines, will be amended to note that the products are now withdrawn from use/discontinued	FTEAM
	• the current website entry for chlorpromazine 50mg/2mL solution for injection ampoules (Largactil®) will be amended to note that this formulation is now withdrawn from use/discontinued.	FTEAM
	The Mental Health Service is aware of the discontinuation and will confirm if there is a local need for the unlicensed injection.	
	• risankizumab (Skyrizi®) is included on the formulary for the treatment of adults with moderate to severe plaque psoriasis in line with SMC 2196. The initial presentation, 75mg/0.83mL solution for injection pre-filled syringe, has been replaced by a higher 150mg strength preparation. The PAS was updated to include the new strength and the change is cost-neutral.	
	No action required on the formulary website but the decision for SMC 2196 will be re-published to note that the strength of risankizumab has increased.	FTEAM

7. OTHER BUSINESS

7.1. SBAR LIOTHYRONINE CAPSULES

Members discussed the SBAR outlining the availability of a new capsule formulation of liothyronine and the principles of generic prescribing and supporting the Scottish Drug Tariff (SDT).

Ms Doney confirmed that a decision to use a non-tariff product does not sit with the Formulary Group but it would be useful to pass the Group's comments to the relevant medicines management groups.

The Group noted:

- NHS Grampian supports generic prescribing, and encourages prescribing of strengths and formulations that are included in the SDT
- liothyronine:
  - is a second-choice agent, with prescribing subject to a local prescribing protocol [used in combination with levothyroxine] for a small defined patient group with treatment initiated by the specialist service
  - is now available as two oral formulations, tablets and capsules. Both presentations are available in three strengths, 5, 10, and 20micrograms, and access to all three strengths allows flexibility in dosing.
  - as the 20microgram tablet, is the only strength currently included on the SDT
  - as the new hard capsule formulation [all strengths], costs significantly less than the tablet formulation
- review of the prescribing data shows that the non-tariff strengths account for the majority of prescribing [the 5 and 10micrograms strengths account for ~ 85% (by quantity)]

Members considered the case for using a different formulation than the tariff preparation. Members supported using the most cost-effective method of prescribing because this is a small clearly defined group of patients, with the majority of prescribing lying with the non-tariff strengths. Members supported generic prescribing and were open to allowing the specialist service to prescribe a non-tariff formulation if it is clinically appropriate and the most cost-effective preparation for the patient.

7.2. SIGN 165: POSITION STATEMENT: LONG-ACTING INJECTABLE BUPRENORPHINE FOR OPIOID SUBSTITUTION THERAPY

The Group noted the release of a national position statement (SIGN 165) regarding the use of long-acting injectable buprenorphine for opioid substitution therapy.

ITEM	SUBJECT	ACTION

Ms Doney reported that NHS Grampian already has guidance in place for the use of Buvidal®. The Substance Misuse Pharmacists and colleagues in the Medicines Management Team will review the SIGN publication and consider if the local guidance should be updated with information from SIGN 165.

7.3. PHARMACY FIRST APPROVED LIST REVIEW

Ms Doney confirmed that following review and release of the NHS Pharmacy First Approved List (October 2021), the plan is to the review the Approved List every two years rather than annually. The next update is planned for publication October 2023.

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2448 - BUDESONIDE (MICROSCOPIC COLITIS)

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

The Group considered the request for budesonide for the induction of remission in patients with active microscopic colitis.

The Group noted:

- budesonide as Cortiment® prolonged release tablet:
  - has a multi-matrix (MMX) structure covered by a gastro-resistant coating that dissolves in intestinal fluids with a pH >7 and releases budesonide at a controlled rate throughout the colon
  - is included on formulary for the induction of remission of mild to moderate ulcerative colitis in adults who present with active left-sided disease and/or proctosigmoiditis
  - has a recommended daily dose of 9mg in the morning for up to 8 weeks and it may be useful to gradually reduce the dose when treatment is discontinued
  - results in lower systemic steroid levels than conventional oral glucocorticoid therapy
  - [for this indication] will replace Budenofalk® and Entocort®, and due to licensing differences the other budesonide preparations will remain on formulary
- the service has stated the at the end of the treatment course the dose will gradually be reduced over 2-4 weeks

Members supported prescribing in Primary Care on the recommendation of a specialist, but requested that the service provided clearer guidance about how the dose should be tapered at the end of treatment. **FTEAM**

The Group accepted the restricted local need for budesonide for the induction of remission in patients with active microscopic colitis, as outlined in SMC 2448.

SMC 2448 - Budesonide 9mg prolonged release tablet (Cortiment®) is routinely available in line with national guidance (SMC 2448).
Indication under review: induction of remission in patients with active microscopic colitis.
Cortiment® offers a prolonged release formulation of budesonide for this indication. Other oral budesonide formulations are available at lower cost.
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**

8.2. FG1 446/22 AND FG1 447/22 - PROGESTERONE (THREATENED MISCARRIAGE)

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

ITEM	SUBJECT	ACTION

The Group considered the request for the use of vaginal micronised progesterone for the management of threatened miscarriage in women with vaginal bleeding who have a confirmed pregnancy, with a history of one or more previous miscarriages, as per NICE Guideline 126 "Ectopic pregnancy and miscarriage: diagnosis and initial management" (NG126).

The Group noted:

- Cyclogest® pessaries and Utrogestan Vaginal® capsules are both considered micronised progesterone, and neither is licensed for the indication under review
- off-label use of micronised progesterone for this indication is supported by NG126
- the service:
  - plans to use either Cyclogest® or Utrogestan Vaginal® at a dose of 400mg twice daily until 12 weeks gestation. Concerns have been raised by experts in Early Pregnancy in the UK that there is no scientific benefit of using beyond 12 weeks as placental function is in place by 12 weeks. However, women may request to continue treatment up to 16 weeks gestation in line with NG126.
  - proposes that an initial two weeks supply is prescribed from the hospital, with subsequent supplies provided by Primary Care, however the split supply is not supported by the GP sub group
  - requested that Cyclogest® 200mg pessaries are included on the formulary in case there are supply problems with the 400mg pessaries
- this is a new costs to the service
- Utrogestan Vaginal® costs significantly more than Cyclogest® pessaries
- Utrogestan® is available as an oral tablet and vaginal capsule so care should be taken to ensure that the correct preparation is prescribed and dispensed, particularly if prescribing were to be transferred to Primary Care
- the cost differential between Cylogest® 400mg pessaries, Cylogest® 200mg pessaries, and Utrogestan Vaginal® 200mg capsules
- medicines are not generally included on the formulary to accommodate the potential for shortages

Due to the significant cost difference between Cyclogest® pessaries and Utrogestan Vaginal®, the Group requested clarification of the clinical circumstances when Utrogestan Vaginal® would be considered for prescribing. **FTEAM**

The Group agreed that the Early Pregnancy Service has the relevant experience dealing with this patient group, and as this is a relatively short-term treatment, the managed service should supply the whole treatment course.

The Group accepted the restricted local need for micronised progesterone 400mg pessaries (Cyclogest®) for the management of threatened miscarriage in women with vaginal bleeding who have a confirmed pregnancy, with a history of one or more previous miscarriages, as per NG126.

Micronised progesterone 400mg pessaries (Cyclogest®) is routinely available in line with local guidance.
Indication under review: [off-label use] management of threatened miscarriage in women with vaginal bleeding who have a confirmed pregnancy and with a history of one or more previous miscarriages.
Restriction: in line with local guideline 'Management of threatened miscarriage (including the use of progesterone where applicable)'.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. **FTEAM**

Micronised progesterone 200mg pessaries (Cyclogest®) and 200mg vaginal capsules (Utrogestan Vaginal®) decision deferred to a future meeting.
Indication under review: [off-label use] management of threatened miscarriage in women with vaginal bleeding who have a confirmed pregnancy and with a history

of one or more previous miscarriages.
Restriction: in line with local guideline 'Management of threatened miscarriage (including the use of progesterone where applicable)'.
Decision deferred to a future meeting. **FTEAM**

8.3. FG1 SMC 2405 - BEROTRALSTAT (HEREDITARY ANGIOEDEMA)

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

The Group considered the request for berotralstat for the routine prevention of recurrent attacks of hereditary angioedema (HAE) in adults and adolescents aged 12 years and older who experience two or more clinically significant attacks per month.

The Group noted:

- berotralstat
  - inhibits plasma kallikrein which is a serine protease that cleaves high molecular weight kininogen
  - is taken as an oral dose of 150mg once daily
  - has limited data in adolescents (only four were included in both the berotralstat 150mg and placebo groups) and the elderly population (no patient was ≥75 years old)
  - will be utilised infrequently and on a selective, unpredictable, intermittent and individually relevant basis only
  - cannot be prescribed in primary care
  - provides an oral option which may be more convenient for patients, with less service implications compared to the alternative(s)
  - [for this indication] meets SMC orphan equivalent criteria and was accepted for restricted use within NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers
- long term efficacy and safety remains uncertain as only 21 patients completed 24 months of treatment with berotralstat
- the service will consider treatment discontinuation, in discussion with patients, where angioedema attack rates do not reduce by at least 50% after three months of treatment and where individual attack severity remains substantially unmodified by treatment
- patient numbers are expected to be very small
- initially the service plans to supply via secondary care but may consider homecare supply in the future
- cost offset is available from replacement of alternate options, e.g., lanadelumab
- the paediatric service supports the submission, and although adolescent patient numbers would be exceptionally small, the service would like to have berotralstat included on the formulary for adolescents in the event that a local need arose
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of berotralstat

The Group accepted the restricted local need for berotralstat for routine prevention of recurrent attacks of HAE in adults and adolescents aged 12 years and older who experience two or more clinically significant attacks per month, as outlined in SMC 2405.

SMC 2405 Berotralstat 150mg hard capsules (Orladeyo®) ▼ is routinely available in line with national guidance (SMC 2405).
Indication under review: routine prevention of recurrent attacks of hereditary angioedema (HAE) in adults and adolescents aged 12 years and older who experience two or more clinically significant attacks per month.
In a phase III study in patients with HAE, berotralstat reduced the attack rate 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

ITEM	SUBJECT	ACTION
	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**
	Discussions for items 8.4, 8.5 and 8.6 were deferred to the next meeting due to technical difficulties.	**FTEAM**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED APRIL 2022

The Group noted the SMC provisional advice issued April 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 APRIL 2022

The Group noted the SMC advice published April 2022.

Following publication of the non-submission statements, for belimumab (Benlysta®) ▼ SMC 2483, carfilzomib (Kyprolis®) SMC 2484 and ibrutinib (Imbruvica®) SMC 2485, 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 2412 venetoclax (Venclyxto®) ▼ (submission expected)
- SMC 2417 upadacitinib (Rinvoq®) ▼ (submission expected)
- SMC 2459 risankizumab (Skyrizi®) ▼ (clinicians not responded)
- SMC 2462 fedratinib (Inrebic®) ▼ (submission expected)

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

SMC 2413 – ATIDARSAGENE AUTOTEMCEL (METACHROMATIC LEUKODYSTROPHY (MLD))

Due to technical difficulties during the meeting, the Group deferred discussion of atidarsagene autotemcel 2 to 10 x 10^6 cells/mL dispersion for infusion (Libmeldy®) until the next meeting. **FTEAM**

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM – APRIL 2022

None.

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update March 2022), 12.2 (Antimicrobial Management Team minute January 2022), 12.3 (Grampian Area Drug and Therapeutics Committee (GADTC) minute September 2021), 12.4 (GADTC minute January 2022), 12.5 (Grampian Primary Care Prescribing Group minute January 2022), and 12.6 (Sharing Learning Points Emollients adverse drug reactions) were noted.

ITEM	SUBJECT	ACTION

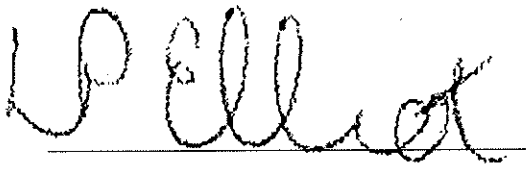
13. AOCB

The Chair announced that Ms Hay gave birth to a baby boy. Congratulations to Ms Hay.

The Chair confirmed that Dr Fitton is retiring, and this is her last meeting.
The Chair thanked Dr Fitton for the valuable and well-informed contributions that she has made at the meetings.
Members wished her all the best in her retirement.

DATE OF NEXT MEETING

Tuesday 17 May 2022 starting at 14:30 via Microsoft Teams

CHAIR'S SIGNATURE  **DATE 17 MAY 2022**