NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 17 September 2019 at 14:30 in the Seminar Room, David Anderson Building

PRESENT	**APOLOGIES**	**APPROVED**
Ms A Davie	Dr D Culligan	
Ms F Doney	Mrs L Harper	
Dr L Elliot	Mr C Rore	
Dr J Fitton	Dr A Sun	
Ms M Galvin		
Dr A MacDonald		
Professor J McLay (Chairman)		
Mrs L Montgomery		
Dr W Moore		
Mr M Paterson		
Mr R Sivewright		

IN ATTENDANCE
Ms Caitlin Wilkinson, Formulary Team administrator.

ITEM	**SUBJECT**	**ACTION**
	The Chairman 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 20 AUGUST 2019**	
	The Group accepted the draft note of the meeting subject to agreement that page 2 (item 6.1 second last paragraph would read "…Primary Consultant should take…"; and minor wording changes to page 5 item 7.2 and page 8 item 12.1.	
	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	
	Noted.	
	4.1.1. MELATONIN PRESCRIBING	
	Ms Doney confirmed that melatonin prescribing was discussed at the recent Grampian Area Drug and Therapeutics Committee (GADTC) meeting. The Director of Pharmacy will issue an updated interim position reiterating that patients should be maintained on their existing formulations [where it remains clinically appropriate].	
	Local guidance will be updated by the end of the calendar year. Stakeholders from Learning Disability Service, Child and Adolescent Mental Health Services (CAMHS), Paediatric Community Services, Primary Care Prescribing Group and Formulary Group will be involved in the update.	
	4.1.2. BOWEL CLEANSING PREPARATIONS	
	At the August meeting, a request was received to use a specific bowel-cleansing preparation. The Group requested some additional information from the service, feedback is awaited.	
	4.1.3. FAST Study	
	The Chairman confirmed that the FAST Study organisers are planning to send letters to enrolled patients and General Practices regarding the prescribing restrictions for febuxostat. The letters are still in draft, but will be shared when finalised.	**FD**

ITEM	SUBJECT	ACTION

The study organisers have received confirmation from the Medicines and Healthcare products Regulatory Agency (MHRA) that the FAST Study can continue.

5. FORMULARY GROUP DECISIONS AUGUST 2019 - PUBLISHED 02/09/2019

5.1. FORMULARY GROUP DECISIONS AUGUST 2019

Members ratified the decisions of the August 2019 meeting as published.

6. NETFORMULARY/FORMULARY REVIEW

6.1. FORMULARY WORK PROGRAMME

Ms Doney confirmed that the formulary work programme would be reported regularly at meetings. The work programme will inform the Group of the progress updating the formulary webpages.
Ms Doney apologised that the document was not issued with the papers, however an update will be available for the next meeting. **FD**

6.2. CAPHOSOL® (UPDATE RE FORMULARY STATUS)

Ms Doney reported that Caphosol® supersaturated calcium phosphate rinse is included on the formulary for specific patient groups, e.g. patients undergoing radiotherapy for head and neck cancer. The North Cancer Alliance (NCA), formerly NOSCAN, issued a guideline for the prevention and treatment of oral mucositis in adult haematology and oncology patients which states that in NHS Grampian [and NHS Highland] Caphosol® is not recommended.

Ms Galvin confirmed that Caphosol® rinse is used locally, it is a medical device so not prescribed but supplied at clinics.

Ms Doney confirmed that:
- there have been requests for colleagues in Primary Care to prescribe Caphosol®
- Caphosol® tablets are now available but have not been requested for use locally
- the process for constituent Boards to ratify NCA guidance has still to be clarified

The Group noted the discrepancy between the NCA guideline and the local formulary status. It was felt that the regional NCA guideline should reflect practice across the region. The Group supported no change to formulary status pending clarification of the regional treatment preferences.

Ms Galvin will liaise with:
- the service(s) and colleagues in the NCA to confirm the review date of the guideline and how to review the information to best reflect practice across the region
- colleagues in Tayside to confirm their experience of the use of Caphosol® tablets **MG**

It was confirmed that Caphosol® is usually supplied to patients at clinic attendance, so requests for Primary Care prescribing should be minimal.

6.3. NICE HYPERTENSION IN ADULTS

The Chairman highlighted the NICE guidance update - hypertension in adults (diagnoses and treatment). The NICE guidance notes hypertensive patients under 80 years of age with an estimated 10 year risk of CVD ≥10% should be offered BP lowering drugs (previously set at 20%).

6.4. MAVIRET® SHORTER TREATMENT DURATION

The Group noted that the licence change for Maviret®, a formulary medicine used for the treatment of chronic hepatitis C virus (HCV) infection, is considered out of remit for the SMC.
The change to licence updates the treatment duration from 12 weeks to 8 weeks for genotype 1, 2, 4-6 for cirrhosis; genotype 3 at 12 weeks for cirrhosis.

The Group accepted the change in treatment duration without the need for a submission. **FTeam**

ITEM	SUBJECT	ACTION

6.5. DIABETIC MEDICINES REVIEW

The Group discussed the two documents issued prior to the meeting.

The Diabetic specialist service has proposed revision of the local treatment guidance for the pharmacological management of type 2 diabetes. The draft guidance proposes changes in prescribing recommendations for second-line medicines, with an increased use of medicines with cardiovascular benefit, e.g. sodium-glucose cotransporter-2 (SGLT-2) inhibitors and glucagon-like peptide 1 (GLP-1) receptor analogues.

The suggested SGLT-2 inhibitors, empagliflozin and canagliflozin are included on the formulary, and the suggested GLP-1 receptor analogues are liraglutide and semaglutide. However, semaglutide is not currently included on the formulary. Ms Doney confirmed that the current GLP-1 receptor analogues included on the formulary are liraglutide, exenatide and lixisenatide.

The Group noted that:

- many people with type 2 diabetes will have cardiovascular disease
- the evidence base for diabetic medicines with [positive] cardiovascular data is growing and the draft guidance is based on currently available cardiovascular data
- empagliflozin and canagliflozin are already included on the formulary, and have published cardiovascular data
- liraglutide and semaglutide are accepted by SMC and have published cardiovascular data. The Diabetic service wishes to include semaglutide on the formulary in preference to GLP-1 receptor analogues without positive cardiovascular data.
- the cost difference between sulphonylureas and SGLT-2 inhibitors and GLP-1 receptor analogues is significant
- the publication "Quality Prescribing for Diabetes a Guide for Improvement 2017-2020" notes that changes in prescribing are anticipated in line with evidence, with an expected increase in use of medicines with cardiovascular benefit (and reduction in use of those without)

It was confirmed that:

- the financial implications of a potential change of second-line choices have been highlighted to the Director of Pharmacy.
- the guidance is in draft and when finalised it will include the relevant publication and review dates. If members have any comments on the guidance, feedback should be sent to Ms Doney within 7 working days. **All**
- the proposed changes are in line with international guidance, with greater use of medicines with cardiovascular benefit, and adopting a personalised approach to diabetes care (tailored to the needs and circumstances of the person with type 2 diabetes)

The Group requested additional data from the Diabetic service, including a submission for the relevant GLP-1 receptor analogue, with information about the decision-making regarding the change in GLP-1 receptor analogue choices, and an estimate of the financial impact of the change of second-line choices.
The submission or SBAR presented to the Group should demonstrate the case for change of recommendations and the consequences of the change(s). **FTeam**

7. OTHER BUSINESS

7.1. INDEPENDENT ADVISORY GROUP

The Group noted publication of the Independent Advisory Group (Tayside Breast Cancer) report. The Chairman highlighted the recommendations listed at the back of the document.

7.2. TUMOUR-AGNOSTIC INDICATIONS BRIEFING DOCUMENT

The Group noted the content of the SMC Horizon Scanning Team publication - Tumour Agnostic Indication Briefing Document. The document provides an overview of the first cancer medicines expected to be licensed for tumour-agnostic (histology-independent) indications, and the implications associated with their introduction into practice.

ITEM	SUBJECT	ACTION

Medicines with tumour-agnostic indications are precision medicines targeted at tumours based on their genetic characteristics rather than their histopathology. The medicines will be licensed based on the genetic target in histology-independent indications, with eligible patients selected by genetic testing. In some tumours, the marker(s) will be very rare, in others the marker(s) will be very common, meaning that identification of eligible patients [for tumour-agnostic therapies] will have major implications for the molecular genetics and pathology specialist services.

7.3. NHS GRAMPIAN DRUG AND ALCOHOL FORMULARY (DRAFT 1)

The Group noted the content of the document, NHS Grampian Drug and Alcohol Services Formulary, produced by the Specialist Pharmacist in Substance Misuse.

It was confirmed that the document is targeted at Substance Misuse Service (SMS) staff and Primary Care colleagues who work collaboratively in delivering care. It aims to give clarity to SMS medics, GPs and Community Mental Health Nurses involved in the clinical assessment and management of patients as to which medicines are routinely prescribed for the management of substance misuse and some basic information on what constitutes standard practice.

The Group considered the document:

- was a useful tool that brings information together in one place, rationalises current practice and gives a formal structure to what is undertaken within the SMS
- a local expert clinical guidance document that included formulary medicines
- was 'owned' by the specialist service

The Group agreed the document was very useful and whilst grateful for sight of the document considered that ongoing review and ratification lies with the Mental Health Operational Medicines Management Group.

7.4. NHS GRAMPIAN PRICE CONFIDENTIALITY GUIDELINE (DRAFT)

The Group considered the draft price confidentiality guideline and members were reminded of the requirement not to share papers/disclose details of discussions from the meeting.

The document is a reminder that many prices are commercial in confidence and should not be disclosed. The document is still in draft, any feedback or comments should be directed to the Director of Pharmacy and copied to Ms Doney.

In response to a query about medicines that are subject to rebates/discounts Ms Doney confirmed that she has asked that National Procurement consider authorising standard wording that Boards can use to highlight when medicines are subject to confidential discounts/rebates. **FD**

Ms Davie asked for confirmation of the circulation and scope of this document as it is badged as NHS Grampian. However, at times there is a need to share financial information with colleagues in the Integration Joint Boards who are not NHS Grampian employees. **DP**

7.5. EMA NEW MEASURES TO AVOID POTENTIALLY FATAL DOSING ERRORS WITH METHOTREXATE FOR INFLAMMATORY DISEASE PUBLISHED AUGUST 2019

The Group noted the European Medicines Agency (EMA) has recommended new measures to prevent serious and potentially fatal errors with the dosing of methotrexate for treating inflammatory diseases.

7.6. PRAC STARTS REVIEW OF DATA ON SKIN CANCER WITH PICATO®

The Group noted that the EMA Pharmacovigilance Risk Assessment Committee (PRAC) has started a review of data on skin cancer in patients using Picato®.

Ms Doney confirmed that Picato® is a formulary medicine and the PRAC recommendations have been shared with the Dermatology Service.

ITEM	SUBJECT	ACTION

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2104 – ANAKINRA (ADULT ONSET STILL'S DISEASE (AOSD))

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

The Group considered the request for anakinra for the treatment of Adult-Onset Still's Disease (AOSD).

The Group noted:
- anakinra:
  - provides a licensed treatment option for AOSD and meets SMC orphan equivalent criteria for this indication
  - [for this indication] can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying anti-rheumatic drugs (DMARDs)
  - is already included on the formulary for the treatment of paediatric Still's disease, including Systemic Juvenile Idiopathic Arthritis (sJIA)
- AOSD is a rare systemic disorder and patient numbers are expected to be low
- that the study data was based on exceedingly small numbers and there are no head-to-head data against biologic comparators, e.g. tocilizumab

The Group accepted the restricted local need for anakinra for the treatment of AOSD, as outlined in SMC 2104.

SMC 2104 – Anakinra 100mg/0.67mL (150mg/mL) solution for injection in prefilled syringe (Kineret®) is routinely available in line with national guidance (SMC 2104). Indication under review: in adults for the treatment of Adult-Onset Still's Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. Anakinra can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying antirheumatic drugs (DMARDs).
It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of Still's disease. **FTeam**

8.2. FG1 420/19 – MICRONISED PROGESTERONE ORAL CAPSULES (UTROGESTAN®) (HRT)

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

The Group considered the request for micronised progesterone (Utrogestan®) oral capsules, as hormone replacement therapy (HRT) - for adjunctive use with oestrogen in post-menopausal women with an intact uterus.

The Group noted:
- Utrogestan® (micronised progesterone oral capsules):
  - is now recommended by the British Menopause Society and Scottish Menopausal Interest Group
  - was assessed by SMC in 2009, and following a full submission it was not recommended for use in NHS Scotland as the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC
  - costs approximately £55 annually per patient
  - is included on the NHS Tayside formulary, with the same positioning requested by the local specialists
- that the submission restricts use to a second-line choice, only to be started at NHS Grampian specialist menopause clinics, with review at three-months before potentially recommending continuation of prescribing in Primary Care
- there are limited prescribing options if patients are intolerant to the adverse effects of synthetic progestogens, and if available [Utrogestan® oral capsules] would provide an oral treatment option with a potentially beneficial breast cancer risk and lipid profile
- that micronised progesterone oral capsules would be replacing an alternative

progestogen
- the current HRT shortages will affect the ability for women to access HRT products

The risk of a potential prescribing error with Utrogestan® oral and vaginal capsules was discussed. Ms Doney will confirm how the medicines are displayed on prescribing systems. **FD**

The Group did not identify any new or additional risks related to the prescribing of micronised progesterone oral capsules. General Practitioner members considered that it would be inappropriate to expect a referral to the specialist service before micronised progesterone oral capsules could be considered for prescribing in Primary Care.

The Group accepted the restricted local need for micronised progesterone oral capsules as a second-line or alternative choice progestogen for adjunctive use with oestrogen in post-menopausal women with an intact uterus, as HRT.

FG1 420/19 - Micronised progesterone 100mg oral capsules (Utrogestan®) is routinely available in line with local guidance.
Indication under review: for adjunctive use with oestrogen in post-menopausal women with an intact uterus, as hormone replacement therapy (HRT).
Restrictions: as
1) a second-line in women who suffer or have suffered moderate or severe progestogenic side effects when using combined HRT preparations or with other progestogens as part of HRT, contraception or bleeding control
2) an alternative progestogen in women with an increased risk of breast cancer, cardiovascular disease (CVD) or venous thromboembolism (VTE) and do not have an absolute contra-indication to HRT.
It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care. **FTeam**

8.3. FG1SMC 2205 - DOLUTEGRAVIR/LAMIVUDINE 50MG/300MG FILM-COATED TABLETS (DOVATO®) ▼ (HIV-1)

Dr Fitton declared a personal specific interest in relation to this product and took no part in decision-making.

The Group considered the request for Dovato® ▼ for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

The Group noted:
- Dovato® ▼:
  - is a fixed-dose combination tablet containing two formulary medicines, dolutegravir and lamivudine
  - offers a single tablet preparation with a lower pill burden and no major financial implications [when compared to use of the individual components]
- the individual component drugs will remain on formulary

The Group accepted the restricted local need for Dovato®, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40kg, as outlined in SMC 2205.

SMC 2205 - Dolutegravir/lamivudine 50mg/300mg film-coated tablets (Dovato®) ▼ is routinely available in line with national guidance (SMC 2205).
Indication under review: for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dolutegravir/lamivudine and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.

ITEM	SUBJECT	ACTION
	It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be prescribed by physicians experienced in the management of HIV infection.	**FTeam**
	Note: The classification 'hospital use only' does not prevent supply of medicines by Primary Care, e.g. use of hospital-based prescription (HBP) stationery.	
9.	**SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED SEPTEMBER 2019**	
	The Group noted the SMC provisional advice issued September 2019.	
	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.	**FTeam**
10.	**SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED SEPTEMBER 2019**	
	The Group noted the SMC advice published September 2019.	
	Following publication of the negative SMC recommendations for osimertinib (Tagrisso®)▼ SMC 2171 and melatonin (Slentyo®) SMC 2168, and the non-submission statement for eribulin (Halaven®) SMC 2231, 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 2184 dacomitinib (Vizimpro®)▼ (submission expected) • SMC 2170 ospemifene (Senshio®)▼ (submission expected) • SMC 2187 pembrolizumab (Keytruda®)▼ (submission expected)	
	Local advice for these medicines and indications will be included in the September 2019 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'.	**FTeam**
	SMC 2185 - DAPAGLIFLOZIN (TYPE 1 DIABETES MELLITUS)	
	There were no declarations of interest recorded in relation to this product.	
	The Group noted that dapagliflozin is a non-formulary medicine and would be recorded as not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time.	
	SMC 2185 – Dapagliflozin 5mg film coated tablets (Forxiga®) is not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time. Indication under review: in adults for the treatment of insufficiently controlled type 1 diabetes mellitus as an adjunct to insulin in patients with BMI ≥27kg/m^2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy. Dapagliflozin in combination with insulin improved glycaemic control compared with insulin alone in adult patients with inadequately controlled type 1 diabetes. Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time.	**FTeam**
	SMC 2200 - TISAGENLECLEUCEL (DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL))	
	Ms Galvin declared a non-personal, non-specific interest in relation to Novartis Pharmaceuticals UK Ltd.	
	Currently, there is not a centre in Scotland established to administer these medicines.	
	The Group accepted that tisagenlecleucel would be recorded as non-formulary, routinely available from a specialist centre in another health board.	

ITEM	SUBJECT	ACTION
	SMC 2200 - Tisagenlecleucel 1.2 x 10^6 to 6 x 10^8 cells dispersion for infusion (Kymriah®)▼ is routinely available from a specialist centre in another health board. Indication under review: for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy. Tisagenlecleucel was associated with an overall response rate of 53% in a single-arm, open-label, phase II study in patients with relapsed or refractory DLBCL. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tisagenleceucel and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. Routinely available from a specialist centre in another health board.	**FTeam**

11. GENERAL INFORMATION FROM SMC SEPTEMBER 2019 - NONE

12. DOCUMENTS FOR INFORMATION

Item 12.1 (MHRA Drug Safety Update August 2019) and Item 12.3 Grampian Primary Care Prescribing Group minute (May 2019) were noted.

Item 12.2 MHRA Hormone replacement therapy (HRT) further information on the known increased risk of breast cancer with HRT and its persistence after stopping – August 2019

The Group noted the information regarding the new analysis that shows some excess risk of breast cancer persists for more than 10 years after stopping HRT. Ms Doney highlighted the response from the British Menopause Society raising serious concerns about the recommendations in the drug safety alert. Ms Doney will forward a link to the British Menopause Society response after the meeting. **FD**

13. AOCB - NONE

DATE OF NEXT MEETING

Tuesday 19 November 2019 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE  **DATE 19 November 2019**