NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 17 April 2018 at 14:30 in the Seminar Room, David Anderson Building

PRESENT	**APOLOGIES**	**APPROVED**
Dr D Culligan	Dr D Counter	
Ms A Davie (until item 9)	Dr J Fitton	
Ms F Doney	Mrs L Harper	
Dr L Elliot	Dr A MacDonald	
Ms M Galvin		
Mrs L Montgomery		
Dr W Moore		
Professor J McLay (Chairman)		
Mr M Paterson		
Mr C Rore		
Mr R Sivewright		

IN ATTENDANCE
Dr Jane Tighe, Consultant Haematologist, for item 3 presentation on the use of carfilzomib and lenalidomide.

ITEM	**SUBJECT**	**ACTION**
	The Chairman opened the meeting, welcomed members and noted that a quorum was present.	
1.	**APOLOGIES**	
	Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 20 MARCH 2018**	
	The draft note of the March meeting was accepted subject to correction of minor typographical errors.	**FD**
	The final approved minute will be in the public domain within 21 days.	**FTeam**
3.	**PRESENTATION**	
	Dr Tighe, Consultant Haematologist, provided the Group with an overview of the use of carfilzomib and lenalidomide maintenance in the management of multiple myeloma. The Chairman thanked Dr Tighe for attending the meeting, and Dr Tighe left before decision-making.	
4.	**MATTERS ARISING**	
	4.1. ACTION LOG	
	The Chairman reviewed the Action log with the Group to clarify the status of items that were not included on the agenda. NALOXONE NASAL SPRAYS Awaiting feedback from the Specialist Pharmacists in Substance Misuse. This item will remain on the Action log.	
	4.2. SHORT LIFE WORKING GROUP FOR DIRECT ORAL ANTICOAGULANTS	
	Ms Doney confirmed that the Short Life Working Group for direct acting oral anticoagulants is established and meeting dates are being agreed. To progress the work, meetings may be 'virtual', and materials from other Health Boards have already been sent to members. This item will be removed from the Action log.	**FTeam**
	4.3. NICE TA481/TA482 (IMMUNOSUPPRESSIVE THERAPY FOR KIDNEY TRANSPLANT FOR ADULTS, CHILDREN AND ADOLESCENT)	
	The Specialist Renal Pharmacist for the adult service has confirmed that TA481 is referring to initial kidney transplantation that for Grampian patients is undertaken in Edinburgh. Treatment options are led by the specialist centre and some medicines are not used locally, e.g. basiliximab (used at induction only).	

Feedback is still awaited from the Lead Pharmacist Women's and Children's Services. **MF**

As NICE Multiple Technology Appraisals no longer have an official standing in NHS Scotland the Group noted the comments of the Specialist Renal Pharmacist (adult service) and took no further action.
This item will be removed from the Action log. **FTeam**

4.4. PRESCRIBING ADVICE/NEW RECOMMENDATIONS FOR VITAMIN D

The Group reviewed the draft position statement for population level vitamin D supplementation.

The Group was generally supportive of the document with a few queries:
- point 3. iii – is a particular preparation recommended?
- 'Responsible Medical Officer' - which health professionals does this phrase encompass?
- are people of particular ethnic origins, e.g. black people of African or Caribbean origin, considered a separate risk group?

Members to send any further comments to Dr Moore. **All**

4.5. ORAL ANTIHISTAMINES (LOCAL NEED FOR ACRIVASTINE TABLETS)

Ms Doney confirmed that in email correspondence Dr Herriot confirmed that he would support inclusion of acrivastine on the formulary, making it available for general use. The Group considered the suggestions but preferred once-a-day preparations as first-choice agents noting that prescribers could prescribe acrivastine for patients if clinically indicated.

4.6. LOCAL PAIN LADDER ADVICE

No information was found regarding a local pain ladder advice document. The Chairman will source the relevant information for the next meeting. **JMcL**

5. FORMULARY GROUP DECISIONS MARCH 2018 - PUBLISHED 03/04/2018

The Group ratified the advice as published.

6. NETFORMULARY/FORMULARY REVIEW

6.1. ALLERGIC CONJUNCTIVITIS

The Group considered the SBAR that reviewed the current formulary choice topical treatments for allergic conjunctivitis.

Ms Doney gave a brief overview:
- acute allergic conjunctivitis is self-limiting and can resolve without intervention
- for recurring symptoms there is insufficient evidence to recommend one type of eye drop over another
- the current formulary choices are sodium cromoglicate (mast cell stabiliser, first-line) and olopatadine (dual-acting antihistamine/mast cell stabiliser, second-line)
- nedocromil is an alternative mast cell stabiliser. It is prescribed locally (with more prescriptions issued for nedocromil than olopatadine). Unlike sodium cromoglicate, it is licensed for use twice a day increasing to four times daily (sodium cromoglicate is licensed for use four times a day).

Members noted that nedocromil is the second most frequently prescribed agent, and that costs are comparable with sodium cromoglicate. The Group supported inclusion of nedocromil sodium on the formulary without the need for a submission.

Nedocromil sodium 2.0% eye drops is routinely available in line with local guidance. Indication under review: for the prevention, relief and treatment of allergic conjunctivitis, including seasonal allergic conjunctivitis, allergic conjunctivitis and vernal-kerato conjunctivitis. It was classified 1a -available for general use and 8e - treatment may be initiated in either hospital or community.

FTeam

6.2. URSODEOXYCHOLIC ACID

There were no declarations of interest recorded in relation to these products.
The Group considered the Summary of Product Characteristics comparison for several ursodeoxycholic acid preparations.

Ms Doney gave a brief overview:

- ursodeoxycholic acid:
  - as 250mg capsules, is the only strength and formulation currently included on the Scottish Drug Tariff (SDT)
  - as 250mg tablets, is currently only available from one manufacturer and the cost is comparable with the SDT price for the 250mg capsules
  - as 2 x 250mg (either capsules or tablets), is more cost-effective than using the 500mg strength tablet
- the 150mg tablet is the only preparation not licensed for primary biliary cirrhosis
- comparing the preparations on a cost/mg basis the 300mg tablet is the most expensive formulation

A member queried the proportion of branded prescribing noted in the paper. **FD**

The Group agreed that:

- **UDCA as 250mg capsules is the first-choice preparation. A 250mg tablet is available at a comparable cost but this formulation is not included on the SDT.**
- **ScriptSwitch should be used to maximise the use of ursodeoxycholic acid 250mg capsules** **AD/FD**
- **2 x 250mg (capsule or tablet) is more cost-effective than 1 x 500mg tablet**
- **the services should confirm if strengths other than 250mg are required** **FD**

6.3. DOXAZOSIN PRESCRIBING GUIDANCE (FOR INFORMATION)

The Group noted the letters issued to prescribers regarding prescribing doxazosin immediate-release tablets in preference to modified-release tablets.
The Chairman noted that the release-profile of the modified-release tablets could be beneficial for some patients.
Mr Rore noted the information when changing between formulations is not entirely in line with the advice given by the Medicines Information department. Mr Rore will raise his concerns with the author. **CR**

6.4. STATINS

The Group reviewed the draft algorithm for secondary prevention.

Ms Doney confirmed that:

- the European Medicines Agency (EMA) is currently reviewing the evidence for the use of omega-3 acid medicines in patients who have had a heart attack
- rosuvastatin is now included on the Scottish Drug Tariff
- the patent for ezetimibe has just expired, generic prices are currently on a par with the proprietary preparation

Members commented that the algorithm was potentially too complicated and requested clarification on:

- the targets, and use of the term ‘non-HDL’ – does this mean LDL?
- when should patients be referred to the lipid clinic?
- the authors of the algorithm **FD**

7. OTHER BUSINESS

7.1. Review of blood glucose test strips (Type 2 diabetic patients) - update

Ms Doney confirmed that the Diabetic Managed Clinical Network (MCN) is reviewing the choice of blood glucose meters and test strips for Type 2 diabetic patients. The final document will be linked to the formulary and emailed to members when available. **FD**

7.2. Alemtuzumab licence change

Ms Doney reported that the licence for alemtuzumab, a formulary medicine used for

multiple sclerosis (MS), has been extended to include treatment in years 3 and 4.
The SMC will not be reviewing this licence extension and the Service will be contacted to confirm if there is a need to extend use beyond year 2. The lead clinician will be invited to a future meeting to update the Group on the current treatment choices for MS. **FD** **FD**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 1242/17 - CARFILZOMIB (ADULT PATIENTS WITH MULTIPLE MYELOMA)

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

The Group reviewed the submission for carfilzomib for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

The Group noted:

- the nature of myeloma, with patients experiencing a number of relapses and remissions, and that patients are likely to receive all treatment options during the course of their disease
- carfilzomib:
  - is the second proteasome inhibitor (bortezomib was the first) and it provides an additional treatment option
  - has been designated an orphan medicine by the European Medicines Agency (EMA)
  - meets SMC orphan criteria, and was accepted for use in NHS Scotland following application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
- the side-effect profile of carfilzomib, and that it is quite toxic
- Members noted the monitoring requirements, and that monitoring is the responsibility of the managed service

The Group accepted the restricted local need for carfilzomib infusion for adult patients with relapsed or refractory multiple myeloma as outlined in SMC 1242/17.

SMC 1242/17 - Carfilzomib 10mg, 30mg, 60mg powder for solution for infusion (Kyprolis®) ▼ is routinely available in line with national guidance (SMC 1242/17). Indication under review: in combination with dexamethasone alone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Carfilzomib in combination with dexamethasone, compared with another proteasome inhibitor in combination with dexamethasone, increased progression free survival in adults with relapsed or refractory multiple myeloma who had received between one and three previous lines of treatment.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of carfilzomib and is contingent upon the continuing availability of the PAS in NHS Scotland or a 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. Treatment should be supervised by a physician experienced in the use of anti-cancer therapy. **FTeam**

8.2. FG1 404/17 - LENALIDOMIDE (MAINTENANCE FOLLOWING AN AUTOLOGOUS STEM CELL TRANSPLANT FOR MYELOMA)

Dr Culligan declared a person specific interest in Celegene (in relation to another indication). He took no part in decision-making but remained in the room and answered questions from the Chairman.

The Group considered the request for the use of lenalidomide as monotherapy for the maintenance treatment of patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.

The Group noted:

- lenalidomide:
  - is already included on the formulary for other indications, and clinicians are familiar with its use and adverse event profile
  - was granted this extension to licence mid-2017
- lenalidomide maintenance was part of Myeloma XI and this clinical trial is now closed

- there is no cost-effectiveness data available for this indication, and it is unclear if a patient access scheme is available for this indication
- the indication is licensed but the company has not submitted to SMC or NICE. The SMC is in contact with the Marketing Authorisation Holder (MAH) but there is no date for submission yet.

The Group did not support the formulary inclusion of lenalidomide as monotherapy for the maintenance treatment of patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation. Based on the data available, the Group considered that a Health Technology Assessment is required for this indication.

FG1 404/17 - Lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg, 25mg hard capsule (Revlimid®) ▼ is not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time.
Indication under review: for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation to prolong the time to disease progression (progression free survival) and to increase overall survival.
Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED APRIL 2018

The Group noted the SMC provisional advice issued April 2018.

If published next month the non-submission statements, for brentuximab vedotin (Adcetris®) ▼ SMC 2085 and naltrexone/bupropion (Mysimba®) ▼ SMC 2086, will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

SMC 1235/17 - SELEXIPAG (UPTRAVI®) ▼

The Group noted the provisional advice for selexipag a medicine licensed for the treatment of pulmonary arterial hypertension (PAH) in adult patients. Ms Doney confirmed that PAH medicines are generally not included on the formulary because these specialist medicines are supplied by the Scottish Vascular Centre. The Group agreed, that if the SMC advice is published next month, selexipag will not be included on the formulary because it will be initiated, prescribed and supplied by specialists in the Scottish Pulmonary Vascular Unit. **FTeam**

SMC 1332/18 - ICATIBANT ACETATE (FIRAZYR®)

Ms Doney confirmed that icatibant acetate (Firazyr®) is already included on the formulary for adults for the same indication, and the abbreviated SMC advice relates to a licence extension to include patients from 2 years. The Group agreed, that if the SMC advice is published next month, icatibant will be included on the formulary in line with SMC 1332/18 without the need for a full submission. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED APRIL 2018

The Group noted the SMC advice published April 2018.

Following publication of the non-submission statements, for ceritinib (Zykadia®) ▼ SMC 1333/18 and parathyroid hormone (Natpar®) ▼ SMC 1334/18, 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 1313/18 dimethyl fumarate (Skilarence®) (submission expected)
- SMC 1314/18 sarilumab (Kevzara®) ▼
- SMC 1317/18 sofosbuvir/velpatasvir/voxilaprevir (Vosevi®) ▼ (awaiting advice)
- SMC 1139/16 teduglutide (Revestive®) ▼ (submission received)
- SMC 1271/17 sofosbuvir/velpatasvir (Epclusa®) ▼ (awaiting advice)
- SMC 1320/18 ciprofloxacin (Cetraxal®) (submission expected)

Local advice for these medicines and indications will be included in the April 2018 decisions as **'Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts'.** **FTeam**

ASPARAGINASE FOR ACUTE LYMPHOBLASTIC LEUKAEMIA

The Service confirmed there is a need for asparaginase as a component of antineoplastic combination therapy for the treatment of acute lymphoblastic leukaemia (ALL) in children and adults. Patient numbers will be small.

The Group accepted the restricted local need for Spectrila® and Erwinase® for use in antineoplastic combination therapy for the treatment of ALL without the need for full submissions.

SMC 1319/18 - Asparaginase 10,000units powder for concentrate for solution for infusion (Spectrila®) is routinely available in line with national guidance (SMC 1319/18).
Indication under review: as a component of antineoplastic combination therapy for the treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years and adults. It was classified 1b -available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be prescribed and administered by physicians and health care personnel experienced in the use of antineoplastic products. Spectrila® should only be given in a hospital setting where appropriate resuscitation equipment is available. **FTeam**

Erwinia L-asparaginase 10,000 units/vial lyophilisate for solution for injection (Erwinase®) is routinely available in line with local guidance.
Indication under review: in combination with other antineoplastic agents to treat acute lymphoblastic leukaemia. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. . Treatment should be prescribed and administered by physicians and health care personnel experienced in the use of antineoplastic products. **FTeam**

11. GENERAL INFORMATION FROM SMC APRIL 2018

Ms Doney confirmed that:

- SMC will not assess the recent licence extension for fluticasone furoate/vilanterol (Relvar® Ellipta®). [The licence has been extended to include use in the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate for patients already adequately controlled on both inhaled corticosteroid and long-acting beta2-agonist].
- the change does not affect the recent guidance issued by the Managed Clinical Network (MCN)
- local clinicians on the Respiratory MCN are aware of the licence extension and have confirmed that they would like that it is recognised by the Formulary Group

The Group noted the licence extension for both strengths of the formulary medicine Relvar® Ellipta®. **FTeam**

12. DOCUMENTS FOR INFORMATION

Item 12.1 Drug Safety Update for April was not published before the meeting and will be included in the May papers.

Items 12.2 (Grampian Primary Care Prescribing Group minute January 2018) and item 12.3 (CMO Letter – Leaflet and learning package on mesh implants for Primary Care) were noted.

13. AOCB - NONE

DATE OF NEXT MEETING

Tuesday 15 May 2018 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE **DATE 21 May 2018**