NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 18 September 2018 at 14:30 in the Seminar Room, David Anderson Building

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

Attendance failed to reach a quorum – decisions reached will be ratified at a future quorate meeting.

IN ATTENDANCE
Mrs Sally-Ann Chadha, Secretary, Formulary Team.

PRESENTING
Dr Callum Duncan, Consultant Neurologist, and Dr David Watson, General Practitioner with a specialist interest in headache, for item 3.

Note some items were taken outwith agenda order.

ITEM	SUBJECT	ACTION
	The Chairman welcomed members, opened the meeting and noted that attendance at the meeting was not sufficient to meet quorum.	
	It was confirmed that the decisions would be emailed to members, and the recommendations will be ratified at a future quorate meeting.	**FD**
1.	**APOLOGIES**	
	Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 21 AUGUST 2018**	
	Members accepted the draft note of the meeting subject to a minor typographical correction and a format change (page 2, item 4.3 spelling of Esmya®; page 5, format change to separate Dr Meredith's presentation from item 9).	
	The corrected approved minute will be in the public domain within 21 days.	**FD**
3.	**PRESENTATION**	
	This item was taken later in the meeting.	
4.	**MATTERS ARISING**	
	4.1. ACTION LOG	
	Ms Doney clarified the status of items that were not included on the agenda.	
	STATINS Ms Doney confirmed that there is a meeting of the specialists and information will be circulated to members.	
	DROPERIDOL AND HRT Droperidol and HRT items are ongoing, and will remain on the Action log.	
	NEDOCROMIL SODIUM WITHDRAWAL BY MANUFACTURER Ms Doney confirmed that information is published on the formulary website and Ms Davie confirmed that changes have been actioned in Primary Care. Members agreed that this action was now closed and should be removed from the Action log.	**FD**

ITEM	SUBJECT	ACTION

LONG-TERM USE OF BROAD SPECTRUM ANTIBIOTICS IN CYSTIC FIBROSIS PATIENTS

Ms Doney confirmed that the query regarding long-term use of a broad spectrum antibiotic in cystic fibrosis patients remains unanswered. This item will remain on the Action log.

PATIENT ACCESS SCHEME DISCOUNTS

Ms Doney confirmed that the patient access scheme (PAS) discounts for levofloxacin (Quinsair®), colistimethate (Colobreathe®) and tobramycin (Tobi Podhaler®) apply in Primary Care as retrospective rebates. Mr Sivewright confirmed that the rebates are applied to the relevant Health and Social Care Partnership budget line. This item will be removed from the Action log. **FD**

TOLVAPTAN (JINARC®)

Ms Doney confirmed that the licence extension for Jinarc® (for stage 4 polycystic kidney disease) remains open. Colleagues nationally will be contacted as the SMC advice took account of the views from a Patient and Clinician Engagement (PACE) meeting. **FD**

5. FORMULARY GROUP DECISIONS AUGUST 2018 - PUBLISHED 03/09/2018

5.1. FORMULARY GROUP DECISIONS AUGUST 2018

The Group ratified the advice as published.

Ms Doney confirmed that going forward the Group's decisions would be published as a portable document file (PDF). The Group authorised the document for publication. **FTeam**

5.2. DRAFT NETFORMULARY UPDATE FOR AUGUST 2018 FORMULARY GROUP DECISIONS

The Group authorised the August formulary decision entries for publication on the new formulary website subject to minor amendments; dimethyl fumarate entries to include indications; denosumab 120mg to include 'restricted' symbol. **FTeam**

6. NETFORMULARY/FORMULARY REVIEW - NONE

7. OTHER BUSINESS

7.1. MYFORTIC® (MYCOPHENOLATE SODIUM)

Ms Doney advised that an email, issued by the Specialist Renal Pharmacist, advised that the managed service plans to change the 'brand' of mycophenolate sodium that it uses from Myfortic® to Ceptava®. The suggestion is that prescriptions for mycophenolate sodium would be written generically, unlike the first-line choice salt mycophenolate mofetil where branded prescribing is always promoted.

Members discussed the potential that patients may be prescribed the wrong salt inadvertently. To minimise confusion and the risk that a prescription is issued for the wrong salt, members recommended that prescribing of either mycophenolate salt be promoted only as branded medicines. **FD**

7.2. FREESTYLE LIBRE®

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

Ms Doney confirmed that the Grampian Medicines Management Group (GMMG) issued an updated position statement on the use of FreeStyle Libre® in NHS Grampian.

FreeStyle Libre® has been accepted for use in NHS Grampian for people with Type 1 diabetes subject to certain eligibility criteria. People will be supplied with the scanner/meter and first sensor at the Diabetic Clinic with prescriptions for subsequent sensors prescribed in Primary Care.

The link to the FreeStyle Libre® position statement will be emailed to the Group. **FTeam**

ITEM **SUBJECT** **ACTION**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 1328/18 - INOTUZUMAB OZOGAMICIN (RELAPSED/REFRACTORY ALL (ADULTS))

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

The Group reviewed the submission for inotuzumab ozogamicin as monotherapy for the treatment of adults with relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL).

The Group noted that:

- inotuzumab ozogamicin:
  - (for this indication) was accepted for restricted use in NHS Scotland following the output from the PACE process and application of SMC modifiers that can be applied when encountering high cost-effectiveness ratios
  - is an European Medicines Agency designated orphan medicine and meets SMC ultra-orphan and end of life criteria
  - was accepted by SMC for restricted use, restricted to patients who are intended to proceed to stem cell transplantation, so [inotuzumab] would act as a bridge to potentially curative haematopoietic stem cell transplant
  - is expected to be used for two cycles but could be used for a maximum of three cycles
- would be an alternative to blinatumomab, and preparation of blinatumomab provides a higher burden on the aseptic unit
- small patient numbers would be expected
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of inotuzumab

Members accepted the restricted local need for inotuzumab ozogamicin as monotherapy for the treatment of adults with relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL) as outlined in SMC 1328/18.

SMC 1328/18 - Inotuzumab ozogamicin (Besponsa®) ▼ is routinely available in line with national guidance (SMC 1328/18).
Indication under review: as monotherapy for the treatment of adults with relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL).
Adult patients with Philadelphia chromosome positive relapsed or refractory B cell precursor ALL should have failed treatment with at least one tyrosine kinase inhibitor.
Restriction: in patients for whom the intent is to proceed to stem cell transplantation.
A phase III open label randomised controlled study demonstrated improvements in remission rates and overall survival for the patient population under review when treated with inotuzumab ozogamicin compared with standard chemotherapy.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of inotuzumab ozogamicin 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 views from a Patient and Clinician Engagement (PACE) meeting.
It was classified 1b- available for restricted use under specialist supervision and 8a – licensed for hospital use only. Treatment should be administered under the supervision of a physician experienced in the use of cancer therapy and in an environment where full resuscitation facilities are immediately available. **FTeam**

8.2. FG1 410/18 - METHOXYFLURANE (MODERATE TO SEVERE PAIN DUE TO INJURY (ADULTS))

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

Members considered the request from the adult Emergency Department (ED) for the anaesthetic agent methoxyflurane, in a 3mL inhalation vapour liquid (Penthrox®). Penthrox® would be used for the emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain.

ITEM	SUBJECT	ACTION

Members noted that:
- Penthrox® (methoxyflurane):
  - is a single-patient use product
  - is only licensed for use in adults
  - will not be reviewed by SMC
- there is a risk of abuse by staff, and members raised a concern about the possible addictive potential
- the medication will be stored in a locked cupboard as per CEL 28 (2013) Medicines Storage on Hospital In-Patient Wards (https://www.sehd.scot.nhs.uk/mels/CEL2013_28.pdf)
- the product is sealed in the plastic bag provided and disposed in medication waste containers

Members were supportive of the submission feeling that it has a role to play in the ED, and whilst minded to accept to formulary they wished clarification of a few points before making a final decision.

Points for clarification:
- concern about the possible abuse potential – is there a count/sign out and count/sign in process under consideration?
- Disposal. The product will be bagged and disposed of in waste containers, it is assumed this is in cin-bins. Does the size of the product cause an issue for the bins available in the department? Or would this be an issue if the number of patients using the device increased?
- members assumed that patients would not be allowed to leave the hospital with a device but is there a potential that patients would leave the ED (to another ward or home) with a device? Or will there be a process for taking the product back from patients?
- is there a potential that patients would come into the ED using a device? Will Penthrox® be used by paramedics/the ambulance service?
- is there guidance for use being considered? Not only how it should be used and which patients it would be available for but which members of staff could access it? **FTeam**

The submission and the members queries will be sent to the Substance Misuse Pharmacists for comment and as a request to liaise with the adult ED. **FD**

3. PRESENTATION

Dr Callum Duncan and Dr David Watson provided members with a comprehensive update on the use of Botox® for the prophylaxis of headaches in adults with chronic migraine, and new treatments for migraine.

8. 8.3. FG1SMC 2012 - ALECTINIB (ALK-POSITIVE ADVANCED NSCLC)

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

Members considered the submission for alectinib monotherapy for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).

The Group noted:
- alectinib:
  - is the third protein kinase inhibitor licensed for patients ALK-positive advanced NSCLC
  - shows significantly improved progression-free survival in treatment-naïve adults with advanced or recurrent ALK-positive NSCLC
  - has very good CNS penetration, and is tolerated well by patients
- overall survival data is not available [not reached]
- annual patient numbers are small, however the extended length of treatment will produce cumulative patient numbers and an increasing financial impact
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of alectinib

ITEM **SUBJECT** **ACTION**

Members accepted the restricted local need for alectinib monotherapy for the first-line treatment of adult patients with ALK-positive advanced NSCLC.

SMC 2012 - Alectinib (Alecensa®) ▼ is routinely available in line with national guidance (SMC 2012).
Indication under review: as monotherapy for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).
A validated ALK assay is necessary for the selection of ALK-positive NSCLC patients. ALK-positive NSCLC status should be established prior to initiation of alectinib therapy. Treatment with alectinib should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. **FTeam**

8.4. FG1SMC 959/14 - ALEMTUZUMAB (RELAPSING-REMITTING MULTIPLE SCLEROSIS)

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

Members considered the request to allow an additional two treatment courses of alemtuzumab for relapsing-remitting multiple sclerosis (RRMS).

The Group noted:
- alemtuzumab is included on the formulary for adult patients with RRMS with active disease defined by clinical or imaging features in line with SMC 959/14 but only for the first two treatment courses (years 1 and 2)
- the request is for retreatment with a third and potentially fourth treatment course
- this licence extension will not be assessed by SMC
- patient number would be very small
- the original SMC detailed advice document included a sensitivity analysis which assessed the impact of retreatment of a proportion of the eligible population demonstrating that the incremental cost-effectiveness ratio appeared to remain cost effective
- the North of Scotland Boards (including Orkney and Shetland) have a higher incidence of MS

Members accepted the restricted local need for up to an additional two treatment courses of alemtuzumab.

Alemtuzumab 12mg concentrate for solution for infusion (Lemtrada®) is routinely available in line with local guidance.
Indication under review: for adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features.
Restriction: up to two additional treatment courses, as needed, may be considered (third or fourth course).
Treatment should be initiated and supervised by a neurologist experienced in the treatment of patients with MS. Specialists and equipment required for the timely diagnosis and management of the most frequent adverse reactions, especially autoimmune conditions and infections, should be available.
Resources for the management of hypersensitivity and/or anaphylactic reactions should be available. Patients must be given the Patient Alert Card and Patient Guide and be informed about the risks of Lemtrada®. It was classified 1b- available for restricted use under specialist supervision and 8a – licensed for hospital use only. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED SEPTEMBER 2018

The Group noted the SMC provisional advice issued September 2018.

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

The Chairman noted the advice regarding hydrocortisone as the branded preparation

ITEM	SUBJECT	ACTION
	Alkindi®, and queried the relative cost of this preparation.	FTeam
	Members noted publication of the non-submission statement for lenalidomide maintenance, the same indication that the Group reviewed in April 2018.	

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED SEPTEMBER 2018

The Group noted the SMC advice published September 2018.

Following publication of the negative SMC recommendations, for pembrolizumab (Keytruda®) ▼ SMC 1339/18 and obinutuzumab (Gazyvaro®) ▼ SMC 2015, and the non-submission statement, for denosumab (Prolia®) SMC 2117, 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 2011 dupilumab (Dupixent®) ▼ (submission expected)
- SMC 2014 tocilizumab (RoActemra®) (submission expected)
- SMC 2091 dolutegravir/rilpivirine (Juluca®) ▼ (submission expected)
- SMC 2093 bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy®) (submission expected)

Local advice for these medicines and indications will be included in the September 2018 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTeam**

11. GENERAL INFORMATION FROM SMC SEPTEMBER 2018 – NIL OF NOTE

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drugs Safety Update August 2018), 12.2 (Medicines, Guidelines and Policies minute June 2018), 12.3 (Antimicrobial Management Team Minute July 2018), 12.4 (Grampian Primary Care Prescribing Group minute May 2018) and 12.5 (Grampian Medicines Management Group minute July 2018) were noted.

ITEM 12.6 PACS TIER 2 NATIONAL REVIEW PANEL

The Chairman highlighted the request for local participation in Peer Approved Clinical System (PACS) panels. Ms Doney confirmed that the Grampian Medicines Management Group (GMMG) is taking this item forward, and anyone interested should contact the Pharmacy and Medicines Directorate or email the Formulary Team. **All**

13. AOCB

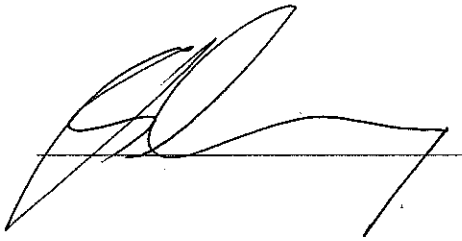
SINGLE NATION FORMULARY

The Chairman queried if there was an update on the progress of the Single National Formulary (SNF).

Ms Doney confirmed that at the September GMMG meeting it was reported that the SNF work is currently paused and the project team is moving to the Pharmacy and Medicines Division of the Scottish Government. Information will be circulated to members. **FD**

DATE OF NEXT MEETING

Tuesday 16 October 2018 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE  **DATE 16 October 2018**