NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 21 March 2017 at 14:30 in Room 218, Suttie Centre, Foresterhill, Aberdeen

PRESENT	APOLOGIES	APPROVED
Dr D Counter	Dr C Hind	
Dr D Culligan (from item 12)	Dr W Moore	
Ms A Davie	Mr M Paterson	
Ms F Doney	Dr A Sun	
Dr L Elliot		
Dr J Fitton		
Mrs L Harper		
Mrs J Jordan		
Dr A MacDonald		
Professor J McLay (Chairman)		
Mrs L Montgomery		
Mr C Rore		
Mr R Sivewright		

ITEM	SUBJECT	ACTION
	The Chairman welcomed everyone to the meeting.	
1.	**APOLOGIES**	
	Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 21 FEBRUARY 2017**	
	The Group accepted the draft note of the meeting held 21 February as an accurate record of the meeting subject to a minor correction to item 12.4.	**FD**
	The corrected approved minute will be in the public domain within 21 days.	**FTeam**
3.	**PRESENTATION - NONE**	
4.	**MATTERS ARISING**	
	4.1. CONFLICTS OF INTEREST	
	It was confirmed that NHS England issued advice to Clinical Commissioning Groups regarding handling conflicts of interest. The NHS England template for publishing information will be used as the basis for publishing members' conflicts of interest.	**FD**
5.	**FORMULARY GROUP DECISIONS FEBRUARY 2017 – PUBLISHED 06/03/2017**	
	The Group ratified the advice as published.	
6.	**NETFORMULARY/FORMULARY REVIEW – NO UPDATE**	
7.	**OTHER BUSINESS**	
	7.1. NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) (MULTIPLE) TECHNOLOGY APPRAISAL (MTA) GUIDANCE - NONE	
	7.2. GUIDANCE FOR LOCAL ELECTIONS	
	Members were reminded that the pre-election period commenced March 13 for the City and Shire, and March 14 for Moray. For NHS staff it starts April 13 (3 weeks pre-election). However if a piece of work is about to begin that has a joint component with an Integrated Joint Board (IJB) or council, members should seek advice from the respective IJB/council.	
	7.3. SBAR ALIROCUMAB (PRALUENT®) ▼ - LICENCE EXTENSION	
	There were no declarations of interest recorded in relation to this product.	
	The Group considered the SBAR outlining the licence extension for alirocumab, a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor that was included on the formulary November 2016.	

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The Group noted:

- when included on the formulary in November, the alirocumab Summary of Product Characteristics (SmPC) noted the dose of alirocumab as – "*the usual starting dose for alirocumab is 75mg administered subcutaneously once every 2 weeks. Patients requiring larger LDL-C reduction (>60%) may be started on 150mg administered subcutaneously (s/c) once every 2 weeks*"
- at the beginning of December section 4.2 of the SmPC was updated to include a 300mg subcutaneous every 4 weeks dose regimen
- the 300mg s/c every 4 weeks regimen is an alternative regimen to the 150mg s/c every 2 weeks for patients requiring larger LDL-C reduction (>60%)
- the change to the SmPC will not be considered by SMC - considered outwith remit because there is no change to the patient population
- there are no cost implications related to the use of this regimen

The Group accepted the restricted local need for the 4-weekly alirocumab 300mg dose regimen without the need for a submission. Use is restricted as outlined in SMC 1147/16, with prescribing and supply limited to the lipid clinic. Classification as per November 2016 formulary decision, 1b- available for restricted use under specialist supervision (prescribing and supply restricted to the lipid clinic) and 8b – recommended for hospital use only. **FTeam**

7.4. SBAR ABIRATERONE (ZYTIGA®) - STRENGTH CHANGE

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

The Group considered the SBAR highlighting that Janssen-Cilag Ltd is marketing a new 500mg strength of abiraterone acetate and the original 250mg tablet will be discontinued 31 August 2017.

The Group noted:

- abiraterone acetate, as the 250mg tablet, is included on the formulary for the management of metastatic castration resistant prostate cancer in line with SMC 764/12 and 873/13
- the recommended dose is 1,000mg as a single daily dose that must not be taken with food. The dose is reduced to 500mg once daily for patients who develop hepatotoxicity during treatment.
- the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abiraterone, and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower
- the Patient Access Scheme Assessment Group has confirmed the PAS applies to the 500mg tablet and that it was included in the PAS from 1 March 2017
- it is not known if the new strength will be considered by SMC, but waiting for SMC provides no advantage to the Board or service

To allow the service time to plan the safe introduction of the 500mg tablet the Group accepted the restricted local need for the new strength abiraterone tablet without the need for a full submission.

Abiraterone acetate 500mg film-coated tablet (Zytiga®) is routinely available in line with national guidance (SMC 764/12, SMC 873/13).
Indication under review: abiraterone acetate is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men:

- **whose disease has progressed on or after a docetaxel-based chemotherapy regimen. Restricted to use in patients who have received only one prior chemotherapy regimen [SMC 764/12]**
- **who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated [SMC 873/13]**

It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be prescribed by an appropriate healthcare professional. **FTeam**

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7.5. SBAR FULVESTRANT (FASLODEX®) - RECLASSIFICATION

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

The Group considered the information submitted requesting reclassification of fulvestrant from 8b – hospital supply only to 8d - treatment may be initiated in Primary Care on the recommendation of a consultant/specialist.

The Group noted:

- fulvestrant 250mg injection (Faslodex®) was included on the formulary May 2016 in line with SMC 114/04. It was approved 'for hospital use only' pending clarification of the mechanisms for transfer to Primary Care (to include prescribing and supply). The Formulary Group also highlighted some concerns around GP prescribing and administration.
- fulvestrant has no specific monitoring requirements
- the specialist oncology consultant will only recommend fulvestrant for patients that fulfil the criteria as described in the SMC advice/formulary statement
- patients will have routine follow up by the hospital consultant usually every three months
- detailed clinic letters will be sent to General Practitioners (GPs) requesting prescription of fulvestrant, with advice to issue prescriptions monthly to minimise waste
- the specialist oncology consultant will advise via clinic letter copied to the GP when treatment should be discontinued
- the mechanisms for reimbursement of fulvestrant (both administration and drug costs) are in place

The Group accepted the request to reclassify fulvestrant injection to allow prescribing in Primary Care on the recommendation of a consultant/specialist. The acceptance is subject to review and update of the information sheet for prescribers. **MG**

SMC 114/04 - Fulvestrant 250mg solution for injection (Faslodex®) is routinely available in line with national guidance (SMC 114/04).
Indication under review: for the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy, or disease progression on therapy with an anti-oestrogen.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of fulvestrant 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 reclassified 1b - available for restricted use under specialist supervision, and 8d - treatment may be initiated in Primary Care on the recommendation of a consultant/specialist. **FTeam**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 1179/16 – LENVATINIB (LENVIMA®) ▼ (DIFFERENTIATED THYROID CANCER REFRACTORY TO RADIOACTIVE IODINE)

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

The Group considered the request for lenvatinib, as Lenvima® ▼, the second oral multikinase inhibitor licensed for the treatment of progressive/locally advanced/metastatic differentiated thyroid cancer (DTC) refractory to radioactive iodine.

The Group noted:

- radioactive iodine resistant differentiated thyroid carcinoma is a rare disease. Before the availability of the oral systemic agents, survival from diagnosis was around 3 years, with a lack of effective alternative therapies.
- patients are discussed at the Regional Thyroid Cancer multidisciplinary team (MDT), and any decision to start treatment is taken by a Consultant Oncologist with advice and discussion from colleagues at the MDT.
- sorafenib was included on the formulary for this indication July 2015

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- there are no comparative data for lenvatinib and sorafenib
- lenvatinib and sorafenib are oral agents that can be given at outpatient clinics
- lenvatinib
  - is given once daily at about the same time each day, with or without food (sorafenib is given twice daily)
  - increases progression-free survival compared to placebo (median PFS 18.3 months versus 3.6 for placebo); overall survival (OS) data is not available (median OS not reached for lenvatinib or placebo groups)
  - was accepted for use in NHS Scotland after application of the appropriate SMC modifiers and the output from the PACE process
  - requires close monitoring during treatment so will be restricted to hospital use only, and treatment should continue as long as a clinical benefit is observed or until unacceptable toxicity occurs
- in the study side-effects were common with 90% [of study participants] requiring dose reduction or interruption; 18% discontinued treatment
- that lenvatinib is also licensed as the brand Kisplyx® ▼ for use in the management of advanced renal cell carcinoma. Kisplyx® ▼ is available as the same salt, formulation and strength capsules.
- the SMC advice for each medicine includes a PAS and takes account of the views of a PACE meeting.

The Group accepted the restricted local need for lenvatinib, as Lenvima® ▼, as outlined in SMC 1179/16.

SMC 1179/16 - Lenvatinib 4mg and 10mg hard capsules (Lenvima®) ▼ is routinely available in line with national guidance (SMC 1179/16).
Indication under review: treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).
Lenvatinib, compared with placebo, significantly improved progression free survival in adults with RAI-refractory DTC.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of lenvatinib 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 8b – recommended for hospital use only. Treatment should be initiated and supervised by a health care professional experienced in the use of anticancer therapies. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED MARCH 2017

The Group noted the SMC provisional advice issued March 2017.

If published next month the negative SMC recommendation, for ticagrelor (Brilique®) SMC 1224/17, and the non-submission statements for, ofatumumab (Arzerra®) SMC 1237/17 and tenofovir alafenamide (Vemlidy®) ▼ SMC 1238/17 will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED MARCH 2017

The Group noted the SMC advice published March 2017.

Following publication of the negative SMC recommendation, for irinotecan hydrochloride (Onivyde®) SMC 1217/17, and the non-submission statements, for abatacept (Orencia®) SMC 1230/17 and lacosamide (Vimpat®) SMC 1231/17, these medicines will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

The following SMC accepted medicine has not been processed within a 60-day timescale:
- SMC 1219/17 obinutuzumab (Gazyvaro®) ▼ - submission expected

Local advice for this medicine and indication will be included in the March 2017 decisions as '**Not routinely available as the ADTC is waiting for further advice from local clinical experts.**' **FTeam**

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11. GENERAL INFORMATION FROM SMC MARCH 2017 - NONE

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update February 2017). A member highlighted the article confirming that electronic Yellow Card reporting of suspected adverse drug reactions is being integrated into Vision, the general practice system software.

Item 12.2 (Minute of Medicines Guidelines and Policies – November 2016) and item 12.3 (Minute of Antimicrobial Meeting December) were noted.

13. AOCB

NYSTATIN DOSE CHANGE - UPDATE

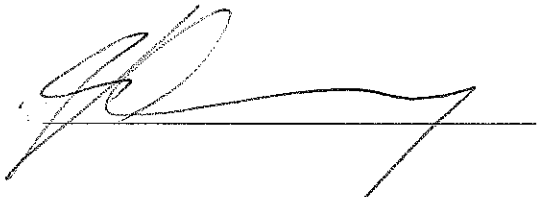
The nystatin dose for oral candidiasis in the BNF historically reflected the posology recommendations in the Nystan® SmPC however, following discussion with the MHRA the dose has been updated (digital versions of the BNF and BNF for Children from March 2017) and now reflects current posology recommendations for generic nystatin products.

It was confirmed that the proposed revisions to the acute and primary care empirical guidance are on hold awaiting comment from the Antimicrobial Management Team. The expectation is that there will be no change to the current published choices but the updates will include the changes highlighting interactions.

The discrepancy between previous published versions of the BNF and BNF for Children and the current electronic versions will be highlighted to prescribers. **AbPhs/ IMPACT**

DATE OF NEXT MEETING

Tuesday 18 April 2017 starting at 14:30 in the Board Room, Aberdeen Royal Infirmary.

CHAIRMAN'S SIGNATURE  **DATE 18 April 2017**