NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 16 January 2018 at 14:30 in the Seminar Room, David Anderson Building

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

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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 19 DECEMBER 2017

The draft minute was not available for the meeting. The Chairman confirmed that both the December and January meeting notes will be reviewed at the February meeting. **FD**

3. PRESENTATION – NONE.

4. MATTERS ARISING

4.1. ACTION LOG

The December Action Log was tabled at the meeting. Members reviewed the Action Log to clarify the status of items that were not included on the agenda.

4.2. EDOXABAN FOR THE TREATMENT OF CANCER-ASSOCIATED VENOUS THROMBOEMBOLISM

Ms Doney confirmed that Dr Watson will attend the February meeting to discuss The New England Journal of Medicine original article “Edoxaban for the Treatment of Cancer-Associated Venous Thromboembolism”.

5. FORMULARY GROUP DECISIONS DECEMBER 2017 - PUBLISHED 02/01/2018

The Group ratified the advice as published, subject to removing the link to formulary choices for items classified as non-formulary. It was felt that in some cases the link to formulary choices could be misleading, particularly for medicines with positive and negative advice.

6. NETFORMULARY/FORMULARY REVIEW

6.1. SBAR - METHYLPHENIDATE MODIFIED RELEASE

The Group considered the SBAR that reviewed the currently available methylphenidate modified-release (MR) tablet formulations.

The Group noted:

- methylphenidate is a central nervous stimulant, Schedule 2 Controlled Drug, used in the management of attention deficit hyperactivity disorder for children (6 years and over), adolescents, and adults. It is available as immediate-release (IR) and MR oral, solid dosage forms. MR preparations should be given as a single dose in the morning and IR preparations should be given in two or three divided doses.
- generic/branded-generic medicines are considered outwith SMC remit so a local assessment is required
- only IR preparations are included in the Scottish Drug Tariff (SDT). Prescriptions for MR methylphenidate should be written by brand name and inclusion of a MR methylphenidate preparation in the SDT is unlikely.
- there are currently four branded-generic MR methylphenidate tablet preparations

marketed in the UK. All show bioequivalence to the reference product Concerta® XL.
- all of the branded-generic MR methylphenidate tablets are half the price of Concerta® XL, Xaggitin® XL also has an additional confidential rebate

The Group supported the proposal to accept Xaggitin® XL tablets to the formulary, noting it as the preferred MR methylphenidate tablet preparation for new patients. Switching patients from Concerta® XL to Xaggitin® XL was supported, with recommendations to switch lead by the specialist service - primary care clinicians would only switch patients on the advice/recommendation of the specialist service.

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

Xaggitin® XL is the preferred MR methylphenidate tablet preparation.

Xaggitin® XL 18mg, 27mg, 36mg, 54mg prolonged-release tablets is routinely available in line with local guidance.
Indication under review: for the second-line treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years. It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in the community on the recommendation of a consultant/specialist. Treatment must be initiated under the supervision of a specialist in childhood and/or adolescent behavioural disorders. **FTeam**

6.2. SBAR - ANTISPASMODICS

The Group discussed the information submitted regarding the prescribing of antispasmodics in Primary Care.

The Group noted:
- that mebeverine hydrochloride 135mg tablets, alverine citrate 60mg capsules and hyoscine butylbromide 10mg tablets are currently the listed on the Scottish Drug Tariff (SDT), and prescriptions for these items should be written generically
- that since Merbentyl® was discontinued, the price of dicycloverine (all formulations) has escalated and the currently available 'generic' products cost 20 to 100 times more than the corresponding Merbentyl® preparation
- that prescriptions for MR mebeverine capsules or any prescriptions for Colofac® (135mg tablets or 200mg MR capsules) cost twice that of generically prescribed mebeverine 135mg tablets
- that mebeverine oral suspension 150mg three times daily costs over £10,000 per annum
- prescriptions for alverine 120mg capsules cost three times more than the equivalent dose prescribed generically as 60mg capsules.
- Fybogel Mebeverine® effervescent granules, contains 3.5g ispaghula husk BP and 135mg mebeverine hydrochloride, cost over three times more than if prescribed generically as individual components
- peppermint oil capsules are not currently listed on the SDT, and the modified-release capsules (Colpermin®) cost significantly more than peppermint oil capsules (Mintec®, Apercap® etc). Colpermin® also contains arachis (peanut) oil.

The Group agreed that:
- **dicycloverine should be removed from formulary, and that patients currently receiving dicycloverine should be reviewed with a view to changing to an antispasmodic listed on the Scottish Drug Tariff (SDT)**
- **prescriptions for mebeverine and alverine should be written generically, and the SDT preparations are the preferred preparations**
- **the standard peppermint oil capsules, gastro-resistant enteric coated, is the preferred peppermint oil preparation**
- **Fybogel Mebeverine® should be noted as non-formulary** **FTeam**

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7. OTHER BUSINESS

7.1. NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) MULTIPLE TECHNOLOGY APPRAISALS - NONE

7.2. NHS ENGLAND PRESCRIPTION CURBS TO FREE UP HUNDREDS OF MILLIONS OF POUNDS FOR FRONTLINE CARE

The Group noted the information issued by NHS England that highlights items that should not be routinely prescribed in primary care.

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 1266/17 - ROLAPITANT (PREVENTION OF DELAYED NAUSEA AND VOMITING)

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

The Group reviewed the submission for rolapitant as a possible option for the prevention of delayed nausea and vomiting in adults undergoing highly emetogenic chemotherapy (HEC).

The Group noted:

- rolapitant:
  - is given as part of a regimen that includes dexamethasone and a 5-Hydroxytryptamine type 3 (5-HT3) receptor antagonist. The dose is 180mg (two tablets) administered within 2 hours prior to initiation of each chemotherapy cycle but at no less than 2-week intervals.
  - is likely to be in patients who could not receive an neurokinin-1 receptor antagonist due to potential drug interactions
  - will provide an additional prophylaxis option for patients receiving HEC
  - will be a specialist use only product
- there is no interaction between rolapitant and dexamethasone, so no dosage adjustment for dexamethasone is required
- the North of Scotland Cancer Network (NOSCAN) antiemetic guideline update is in progress, and will include rolapitant

The Group accepted the restricted local need for rolapitant as a possible treatment option for the prevention of delayed nausea and vomiting in adults undergoing highly emetogenic chemotherapy (HEC).

SMC 1266/17 - Rolapitant (as hydrochloride monohydrate) 90mg film-coated tablets (Varuby®) ▼ is routinely available in line with national guidance (SMC 1266/17). Indication under review: as a first-line option in adults undergoing highly emetogenic chemotherapy (HEC), for the prevention of delayed nausea and vomiting. Rolapitant is given as part of combination therapy.
In phase III studies of patients scheduled to receive highly or moderately emetogenic chemotherapy, a greater proportion of patients treated with rolapitant-based combination therapy achieved a complete response (defined as no emesis or use of rescue medication) in the delayed phase (>24 to 120 hours after initiation of chemotherapy) of cycle one compared with combination therapy alone.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of rolapitant and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. **FTeam**

8.2. FG1SMC 1273/17 - OLARATUMAB (ADVANCED SOFT-TISSUE SARCOMA)

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

The Group reviewed the submission for olaratumab in combination with doxorubicin for the first-line treatment of adult patients with advanced soft-tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy.

The Group noted that:

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- soft-tissue sarcomas are a rare and heterogeneous group of cancers. In patients with advanced or metastatic disease, treatment is likely to be palliative and doxorubicin is considered first-line standard of care with a response rate of 10% to 30%.
- olaratumab:
  - is used in combination with doxorubicin
  - has a conditional marketing authorisation[1] from the European Medicines Agency (EMA) and has been designated as an orphan medicine by the EMA
  - (for this indication) meets SMC end of life and orphan-equivalent criteria, and 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
- other medicines licensed for the treatment of soft-tissue sarcomas are not accepted for use in NHS Scotland
- the local estimate of patient numbers is small (≤5) but in line with the manufacturers estimate

The Group accepted the restricted local need for olaratumab in combination with doxorubicin for the first-line treatment of adult patients with advanced soft-tissue sarcoma as outlined in SMC 1273/17.

SMC 1273/17 - Olaratumab 10mg/mL concentrate for solution for infusion (Lartruvo®)
▼ is routinely available in line with national guidance (SMC 1273/17).
Indication under review: in combination with doxorubicin for the first-line treatment of adult patients with advanced soft-tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy.
In an open-label phase II study, olaratumab in combination with doxorubicin improved progression-free and overall survival compared with doxorubicin alone in patients with advanced soft-tissue sarcoma not amenable to surgery or radiotherapy.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of olaratumab 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 must be initiated and supervised by physicians experienced in oncology. **FTeam**

8.3. FG1SMC 1276/17 - PALBOCICLIB (HR-POSITIVE HER2-NEGATIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER)

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

The Group reviewed the request for palbociclib in combination with an aromatase inhibitor for first-line treatment of HR-positive HER2-negative locally advanced or metastatic breast cancer.

The Group noted:
- palbociclib:
  - is an oral medication that is co-administered with letrozole,
  - is taken orally at a dose of 125mg once daily for 21 consecutive days followed by seven days off treatment to comprise a complete cycle of 28 days; letrozole is taken orally at a dose of 2.5mg once daily continuously throughout the 28-day cycle
  - (for this indication) meets SMC end-of-life criteria and was accepted for restricted use in NHS Scotland following the output from the PACE process
  - is an add-on treatment, and so an additional cost
- hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer is not a rare condition
- treatment with palbociclib should be continued as long as the patient is deriving clinical

[1] The approval of a medicine that address unmet medical needs of patients on the basis of less comprehensive data than normally required. The available data must indicate that the medicine's benefits outweigh its risks and the applicant should be in a position to provide the comprehensive clinical data in the future.

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benefit from therapy or until unacceptable toxicity occurs
- that the time to progression is approximately 2 years, and the budget impact will be significant and cumulative

The Group requested clarification of patient numbers, to confirm if the estimates reflected the cumulative patient numbers or the incident patient numbers. **MG MG/FD**

The Group accepted the restricted local need for palbociclib as outlined in SMC 1276/17.

SMC 1276/17 - Palbociclib 75mg, 100mg, 125mg hard capsules (Ibrance®) ▼ is routinely available in line with national guidance (SMC 1276/17).
Indication under review: in combination with an aromatase inhibitor for first-line treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer:
In an open label phase II study and a double-blind, placebo-controlled phase III study, palbociclib in combination with letrozole increased progression-free survival when compared with letrozole alone in patients with oestrogen receptor-positive, HER2-negative advanced breast cancer.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of palbociclib 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 initiated and supervised by a physician experienced in the use of anticancer medicinal products. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED JANUARY 2018

The Group noted the SMC provisional advice issued January 2018.

If published next month the non-submission statements, for daptomycin (Cubicin®) SMC 1309/18, elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil (as fumarate) (Stribild®) ▼ SMC 1310/18, pasireotide (as pamoate) (Signifor®) SMC 1311/18 and peginterferon alfa-2a (Pegasys®) SMC 1312/18, will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED JANUARY 2018

The Group noted the SMC advice published January 2018.

Following publication of the negative SMC recommendations, for carbetocin (Pabal®) SMC 309/06, eluxadoline (Truberzi®) ▼ SMC 1292/18, nivolumab (Opdivo®) ▼ SMC 1285/18, and obinutuzumab (Gazyvaro®) ▼ SMC 1286/18, and the non-submission statements, for adalimumab (Humira®) SMC 1305/18, ceftaroline fosamil (Zinforo®) SMC 1306/18, ceftazidime/avibactam (Zavicefta®) ▼ SMC 1307/18 and metformin hydrochloride (Glucophage SR®) SMC 1308/18, these medicines will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

SMC 1290/18 - SYMTUZA® (HIV-1)

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

The Group considered Symtuza® ▼ for inclusion on the formulary for the treatment of human immunodeficiency virus (HIV-1) infection in adults and adolescents (aged 12 years and over with body weight at least 40kg).

The Group noted:
- Symtuza® ▼:
  - is a quadruple-component product that will provide a single tablet option rather than patients having to take two dual component tablets, Rezolsta® and Descovy®
  - is licensed from age 12 years (weight ≥40kg) whereas Rezolsta® is licensed from 18 years and older, and Descovy® is licensed aged 12 years and older with body weight

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at least 35 kg

- there is a local need for Symtuza® ▼, and introduction will be cost-neutral to cost-saving

The Group accepted the restricted local need for Symtuza® ▼ for treatment of HIV-1 infection in adults and adolescents (aged 12 years and older with body weight at least 40kg) without the need for a full submission.

SMC 1290/18 - Symtuza® ▼ 800mg/150mg/200mg/10mg film-coated tablet (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) is routinely available in line with national guidance (SMC 1290/18).
Indication under review: the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents (aged 12 years and older with body weight at least 40kg).
SMC has previously accepted darunavir/cobicistat (Rezolsta®) and emtricitabine/tenofovir alafenamide (Descovy®). Symtuza® (darunavir, cobicistat, emtricitabine, tenofovir alafenamide) provides a single-tablet alternative to Rezolsta® plus Descovy® at no additional cost. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated by a physician experienced in the management of HIV-1 infection. **FTeam**

Note: The classification 'recommended for hospital use only' does not prevent supply of medicines by Primary Care, e.g. use of hospital-based prescription (HBP) stationery.

11. GENERAL INFORMATION FROM SMC JANUARY 2018 - NONE

12. DOCUMENTS FOR INFORMATION

Items 12.1, 12.2 (Drug Safety Update December 2017 and January 2018) and Item 12.3 (Grampian Primary Care Prescribing Group minute 15 November 2017) were noted.

13. AOCB - NONE

DATE OF NEXT MEETING

Tuesday 20 February 2018 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE _____ **DATE 20 February 2018**