NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 16 July 2019 at 14:30 in the Seminar Room, David Anderson Building

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

IN ATTENDANCE
Mr Bruce Wilkie, Principal Pharmacist – Supply, for item 3.
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. The Chairman welcomed Ms Caitlin Wilkinson to the meeting. Ms Wilkinson is a new member of the Formulary Team and will attend meetings as minute-taker.	
2.	**DRAFT MINUTE OF THE MEETING HELD 18 JUNE 2019**	
	The Group accepted the draft note of the meeting subject to correction of one bullet point in items 8.1 and 8.2 – changing "SMC ultra-orphan equivalent .." to "SMC orphan-equivalent .. ", and minor typographical changes.	**FD**
	The corrected final approved minute will be in the public domain within 21 days of approval.	**FD**
3.	**PRESENTATION**	
	Mr Wilkie, provided the group with a comprehensive update on medicines homecare arrangements including governance issues and national and local work. Mr Wilkie confirmed that: • a definition of medicines homecare is "the provision of medicines, with or without additional clinical input, to a patient in their home environment; it is normally provided by a commercial company on the behalf of the NHS" • medicines homecare arrangements account for a significant proportion of the NHS Grampian acute medicines spend, and the spend has increased significantly over the past few years • homecare services are only used if they are clinically justified • for patients there are positive and negative aspects to the use of medicines homecare arrangements • all arrangements provide dispense and delivery, but they can extend to include provision of nursing support, supply of equipment, aseptic preparation etc. • governance issues have to be considered in commissioning and managing services, including business continuity concerns. There are national and local processes to ensure the relevant governance (clinical, information, financial) processes are in place. • there is a national group, Medicines Homecare National Governance Medicines Management Group that oversees the governance requirements/arrangements for medicines homecare services in NHS Scotland • to provide continuity of approach, all medicines homecare services approved by the national group are now signed off centrally by National Procurement for all of the Health	

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Boards in NHS Scotland
- there is a local group (NHS Grampian Medicines Homecare Services Group) which oversees the NHS Grampian Homecare Policy. The Group ensures that services are appropriate for NHS Grampian patients and that suitable local governance arrangements are in place.

The Chairman thanked Mr Wilkie for attending the meeting, and Mr Wilkie left the meeting.

4. MATTERS ARISING

4.1. ACTION LOG

Noted.

4.1.1. HRT REVIEW

Ms Doney confirmed that the HRT review is being taken forward linking this with a request for the use of Utrogestan®, a SMC not recommended medicine that specialist colleagues are recommending for prescribing in Primary Care.

4.1.2. PATISIRAN - SMC 2157

This item was discussed under item 7.

5. FORMULARY GROUP DECISIONS JUNE 2019 - PUBLISHED 02/07/2019

5.1. FORMULARY GROUP DECISIONS JUNE 2019

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

6. NETFORMULARY/FORMULARY REVIEW

6.1. MELATONIN

The Group noted the availability of newly licensed melatonin products, and that discussion is required with various groups to progress update of the local melatonin prescribing guidance.

7. OTHER BUSINESS

7.1. NEW APPROACH TO THE ASSESSMENT OF ULTRA-ORPHAN MEDICINES AND

7.2. NUSINERSEN (SPINRAZA®)

Items 4.1.2, 7.1 and 7.2 were taken together.

The Group discussed the new system for the assessment of medicines for very rare diseases (ultra-orphan). Under this pathway, medicines can be made available through the NHS in Scotland for a period of three years prior to a decision on routine use in NHS Scotland. There are a number of criteria that a pharmaceutical company must fulfil if they wish their medicine to be assessed via the new pathway.

The changes mean if a medicine meets the new definition of an ultra-orphan medicine [**and** the Marketing Authorisation Holder chooses to put the medicine through the new ultra-orphan process] and undergoes an appraisal by the Scottish Medicine Consortium (SMC), then it will be available on the NHS in Scotland for up to three years while further evidence on its effectiveness is generated. The SMC will then review the evidence after three years and make a final decision on its routine use in NHS Scotland.

The Group agree that:
- the ADTC does not have a role in the decision-making on the availability of medicines that are considered under the new approach to ultra-orphan medicines so these medicines should be considered out of remit for the Group/ADTC
- medicines that the Scottish Government has made available through the NHS in Scotland via the new ultra-orphan process will be:
  - highlighted to colleagues in finance
  - recorded as not routinely available in NHS Grampian
- under current [local] processes there is a potential for confusion about availability of

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SMC accepted medicines that met the previous SMC ultra-orphan criteria but have not been requested for formulary inclusion because there is not a local need [no patients requiring treatment].

The Group noted that:

- nusinersen was accepted by the SMC for routine use in patients with infantile onset symptomatic type 1 (5q) spinal muscular atrophy (SMA) [SMC 1318/18]. However, because a local need has not been identified a local submission has not been received for this indication.
- nusinersen is now available through the new ultra-orphan pathway for the treatment of type 2 and 3 SMA
- there are local processes available to access medicines that are not routinely available in NHS Grampian/not included on the formulary
- due to the change in process of access to ultra-orphan medicines the Group considered it inappropriate to request a formulary submission for highly specialist 'legacy' SMC accepted ultra-orphan medicines where patient numbers are expected to be exceedingly low, unpredictable or sporadic

The Group agreed that the following highly specialist medicines for very rare conditions that have been accepted by SMC would be recorded as not routinely available in NHS Grampian, however, if a local need is identified the medicines would be available for use:

1) nusinersen for the treatment of 5q spinal muscular atrophy (SMA) in patients with symptomatic type 1 SMA (infantile onset)) [SMC 1318/18] and
2) patisiran for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy [SMC 2157]

SMC 1318/18 - Nusinersen 12mg solution for injection (Spinraza®) ▼ is not routinely available in NHS Grampian.
Indication under review: for the treatment of 5q spinal muscular atrophy (SMA) in patients with symptomatic type 1 SMA (infantile onset)) [SMC 1318/18].
In randomised, controlled, phase III studies of children with SMA, nusinersen treatment was associated with significant improvements in motor function compared with a sham injection. In infants with type I SMA, nusinersen significantly prolonged the time to permanent assisted ventilation or death.
This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nusinersen. This advice 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.
Not routinely available in NHS Grampian. **FTeam**

SMC 2157- Patisiran (Onpattro®) ▼ is not routinely available in NHS Grampian.
Indication under review: the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy.
In a phase III study of adults with hATTR amyloidosis and polyneuropathy, patisiran was associated with significant improvements compared with placebo, measured by the change in modified neuropathy impairment score +7 (mNIS+7) from baseline to 18 months.
This SMC advice takes account of the benefit of a Patient Access Schemes (PAS) that improves the cost- effectiveness of patisiran. This advice 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.
Not routinely available in NHS Grampian. **FTeam**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2156 - DURVALUMAB (LOCALLY ADVANCED, UNRESECTABLE NSCLC)

Dr Fitton declared a personal specific interest in AstraZeneca UK Limited and took no part in decision-making.

Ms Galvin and Mrs Harper declared non-person, non-specific interests in AstraZeneca UK Limited, and took part in decision-making.

The Group considered the request for durvalumab as monotherapy for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on ≥ 1% of tumour cells and whose disease has not progressed following, platinum-based, concurrent chemoradiation therapy.

The Group noted:

- durvalumab:
  - is a fully human, immunoglobulin G1 kappa (IgG1κ) monoclonal antibody that blocks the binding of PD-L1 (programmed cell death ligand 1) to PD-1 (programmed cell death protein 1) and CD-80, resulting in enhanced anti-tumour activity by eliminating the immunosuppressive effects of PD-L1 on cytotoxic T-cells
  - is administered as an intravenous (IV) infusion at a dose of 10mg/kg given over 60 minutes every 2 weeks, until disease progression or unacceptable toxicity, or a maximum of 12 months
  - [for this indication] meets SMC ultra-orphan and end-of-life criteria, and was accepted for use in NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers
  - [for this indication] represents a new cost to the Health Board
- the 42 day treatment window to initiate treatment after completion of concurrent chemoradiation therapy
- the median length treatment in the PACIFIC study was 20 cycles, and the maximum length of treatment is 12 months
- progression-free survival (PFS) was significantly greater for durvalumab compared to placebo [median PFS 17.2 months versus 5.6 months; p<0.0001]
- patient numbers are expected to be low, but the cost of treatment is high
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of durvalumab

The Group accepted the restricted local need for durvalumab as monotherapy for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) as outlined in SMC 2156.

SMC 2156 - Durvalumab 50mg/mL concentrate for solution for infusion (Imfinzi®) ▼ is routinely available in line with national guidance (SMC 2156).
Indication under review: as monotherapy for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 [programmed cell death ligand 1] on ≥1% of tumour cells and whose disease has not progressed following platinum-based concurrent chemoradiation therapy.
Durvalumab, compared with placebo, improved progression-free survival and overall survival in adults who have locally advanced unresectable NSCLC with PD-L1 expressed on ≥1% of tumour cells and disease that has not progressed following platinum-based chemoradiation therapy.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of durvalumab 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 must be initiated and supervised by a physician experienced in the treatment of cancer. Patients with locally advanced NSCLC should be evaluated for treatment based on the tumour expression of PD-L1 confirmed by a validated test. **FTeam**

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8.2. FG1SMC 2134 - ERENUMAB (PROPHYLAXIS OF CHRONIC MIGRAINE IN ADULTS)

Ms Galvin declared a non-person, non-specific interest in Novartis, and took part in decision-making.

The Group considered the request for erenumab for adults with chronic migraine [defined as headaches on at least 15 days per month of which at least 8 days are with migraine] whose condition has failed to respond to three of more prior oral prophylactic treatments].

The Group noted:

- erenumab:
  - is a fully human monoclonal immunoglobulin G2 that is directed against the calcitonin gene-related peptide (CGRP) receptor complex and inhibits the action of CGRP
  - is the first in a new class of agents, CGRP antagonists, specifically developed for the management of migraine
  - is the first of four CGRP antagonists expected to be licensed for use in migraine
  - is given as monotherapy as a 70mg or 140mg subcutaneous injection every 28 days
  - will be available for patient self-administration
  - will be provided using a medicines homecare service
  - is a new agent with positive outcomes [compared to placebo]
- the local estimate of patient numbers appears small, but may reflect clinic capacity
- that proposed use would be supported by a treatment protocol, that includes review timescales, starting and stopping rules; including discontinuation of treatment if insufficient response after an initial 3-month trial
- initially the service plans to use erenumab in 'Botox® failures'
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of erenumab
- the specialists also requested review of the current treatment protocol, reducing the number of prophylactic agents from 6, to 4 or 5
- that sodium valproate [for migraine] is now contraindicated in females of child-bearing age
- fremanezumab is the second CGRP antagonist licensed by the EMA for use in migraine. There is no timeline for SMC review yet. Fremanezumab is available for self-injection by patients and has a possible 3-monthly dosing schedule (225mg once monthly or 675mg every three months).

The Group supported review of the current treatment protocol, reducing the number of prophylactic agents from 6 medicines.

The Group accepted the restricted local need for erenumab for adults with chronic migraine [headaches on at least 15 days per month of which at least 8 days are with migraine] whose condition has failed to respond to three or more prior oral prophylactic treatments].

SMC 2134 - Erenumab 70mg, 140mg solution for injection in pre-filled pen (Aimovig®) ▼ is routinely available in line with local guidance.
Indication under review: adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine) whose condition has failed to respond to ≥ 3 prior oral prophylactic treatments.
In studies in patients with episodic and chronic migraine, erenumab significantly reduced the number of migraine days per month compared with placebo.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of erenumab 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.
Treatment should be initiated by physicians experienced in the diagnosis and treatment of migraine. **FTeam**

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9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED JULY 2019

The Group noted the SMC provisional advice issued July 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 JULY 2019

The Group noted the SMC advice published July 2019.

Following publication of the negative SMC recommendations, for darvadstrocel (Alofisel®) ▼ SMC 2115 and encorafenib (Braftovi®) ▼ SMC 2145, 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 2180 daratumumab (Darzalex®) ▼ (submission expected)
- SMC 2149 palbociclib (Ibrance®) ▼ (submission expected)
- SMC 2181 arsenic trioxide (Trisenox®) (submission expected)

Local advice for these medicines and indications will be included in the July 2019 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTeam**

11. GENERAL INFORMATION FROM SMC JULY 2019

TESTOSTERONE REPLACEMENT THERAPY

Ms Doney confirmed that testosterone-containing products used in testosterone replacement therapy for the treatment of male hypogonadism are now out of remit for SMC assessment.

Later this year Testim® gel will be marketed in the UK, the Formulary Team will monitor the situation and bring a review to Group when appropriate. **FTeam**

12. DOCUMENTS FOR INFORMATION

ITEMS 12.1 (MHRA DRUG SAFETY UPDATE JUNE 2019)

The Chairman highlighted the article 'Direct-acting oral anticoagulants (DOACs): increased risk of recurrent thrombotic events in patients with antiphospholipid syndrome'. **FTeam**

The Group requested that the practice pharmacist teams identify and refer patients [with antiphospholipid syndrome who are prescribed DOACs] to General Practitioners. **AD**

Items 12.2 (Antimicrobial Management Team Meeting minute March 2019) and 12.3 (Grampian Medicines Management Group minute May 2019) were noted. **FD**

13. AOCB

SCOTTISH DRUG TARIFF UPDATE JULY 2019 – TACROLIMUS 0.1% OINTMENT

Ms Doney discussed the paper emailed the day before the meeting.

Tacrolimus ointment is a formulary medicine, and in July the 0.1% ointment was included on the Scottish Drug Tariff (SDT).

It was confirmed that:

- inclusion of tacrolimus 0.1% ointment on the SDT has the potential to reduce prescribing costs, but only if the current branded prescriptions are reviewed and changed to generic prescriptions [at the current SDT price (July 2019) continuing to prescribe by brand name (Protopic®) will incur an addition £8.10 per 30g pack or £11.64 per 60g pack]
- the current formulary entry has been updated to highlight that tacrolimus ointment should be prescribed by generic name, and removing reference to the brand name

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	Protopic® • inclusion of tacrolimus 0.1% ointment on the SDT and the need to prescribe by generic name will be highlighted to the dermatology service, colleagues in distribution ARI, the Primary Care Prescribing Group and HSCP Lead Pharmacists.	FD
	Ms Davie will progress update of the ScriptSwitch profile to offer a switch from branded to generic prescribing for tacrolimus ointment.	AD
	MEDICINES OFF PATENT – ATOMOXETINE AND SOLIFENACIN	
	Ms Doney confirmed that atomoxetine and solifenacin are now off patent but are not included on the SDT. The next window for inclusion is October and the Formulary Team will keep a watching brief on SDT updates.	FTeam
	The current formulary entries have been updated to highlight that these medicines should be prescribed by generic name, and for atomoxetine any reference to the brand name Strattera® has been removed.	
	The loss of patent will be highlighted to colleagues in acute and primary care, with any update regarding SDT status coming back to a future meeting.	FD
	Ms Davie will progress update of the ScriptSwitch profile to offer a switch from branded to generic prescribing for these medicines.	AD
	DATE OF NEXT MEETING	
	Tuesday 20 August 2019 starting at 14:30 in the Seminar Room, David Anderson Building.	

CHAIRMAN'S SIGNATURE _____ **DATE** **20 August 2019**