NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 18 January 2022 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms L Cameron	Mrs G McKerron	
Ms A Davie	Mr M Paterson	
Ms F Doney		
Dr L Elliot		
Dr J Fitton		
Ms M Galvin		
Professor J McLay (Chairman)		
Dr M Metcalfe		
Mrs L Montgomery		
Mrs K Neave		
Dr J Newmark		
Mrs S O'Beirne		
Mr R Sivewright		

IN ATTENDANCE
Miss Valerie Dick, Pharmacist Team Leader, Women and Children's Service, observer
Ms Christine Hay, Formulary and Medicines Management Pharmacist
Mrs Anne Rembisz, Formulary Team administrator

ITEM	SUBJECT	ACTION
	The Chairman welcomed members, opened the meeting, and noted that a quorum was present. The Chairman welcomed Miss Valerie Dick, Pharmacist Team Leader, Women and Children's Service, to the meeting as an observer.	
1.	**APOLOGIES** Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 21 DECEMBER 2021** The Group accepted the draft note of the meeting subject to minor typographical changes. The corrected final approved minute will be in the public domain within 21 days of approval.	**FD**
3.	**PRESENTATION** None.	
4.	**MATTERS ARISING**	
4.1.	**ACTION LOG** The action log was noted. No additional items were identified that should have been included on the agenda.	**FTEAM**
4.2.	**STATIN INTOLERANCE PATHWAY (NHS ENGLAND)** The Group discussed the Statin Intolerance Pathway produced by NHS England.	

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Ms Doney confirmed that:

- at a previous meeting members requested that the Lipid Service produced guidance to help colleagues to assess statin intolerance
- NHS England has published a "Statin Intolerance Pathway"
- the pathway refers to National Institute for Health and Care Excellence (NICE) health technology appraisals which may or may not be in line with the relevant advice from SMC/Healthcare Improvement Scotland (HIS)
- HIS has not published an equivalent pathway for NHS Scotland
- the pathway was shared with Dr Simpson (and colleagues in the Lipid Service) and Dr Simpson supported adopting the guidance rather than adapting it for local use

Members agreed that the pathway whilst detailed, was clear and would assist prescribers to assess statin intolerance. Members supported adopting the pathway, and disseminating it to colleagues in Primary and Secondary care. **FTEAM**

Ms Doney will discuss the pathway with colleagues in HIS and other Health Boards. **FD**

4.3. ADRENALINE AUTO-INJECTOR PRESCRIBING ADVICE 2021

At the December meeting, Dr Herriot offered to summarise the circumstances in which adrenaline auto-injectors should be prescribed.

The Group agreed that the adrenaline auto-injector prescribing advice provided by Dr Herriot was clear and would be helpful to prescribers and should be disseminated. **FTEAM**

It was confirmed that:

- patient support information/materials are available on the device websites and patients/carers can be directed to the relevant device-specific information
- healthcare professionals can register with the different device websites to receive training device and other supporting information
- Emerade® training devices cannot be ordered to the UK at the moment, however training devices are available for the other devices
- the British Society of Allergy and Clinical Immunology (BSACI) was involved in the production of the Medicines and Healthcare products Regulatory Agency (MHRA) report. The BSACI plans to publish practical primary guidance for adrenaline prescribing for those working in primary care, however, a timeline for release is not available.

4.4. THROMBOPOIETIN RECEPTOR AGONISTS ON FORMULARY INCLUDING LICENCE COMPARISON

At the December meeting members' queried if three thrombopoietin (TPO) receptor agonists are required on formulary, and if there would be a preferred agent.

It was confirmed that:

- there are differences in the licencing (indications and age ranges) of the three TPO receptor agonists
- at the moment, the service would prefer to have three agents on formulary. In clinical practice eltrombopag and romiplostin may remain the first-choice agents, reserving avatrombopag for those patients that do not respond or cannot tolerate first-line choices. However, as experience with avatrombopag increases this may change, and the service will keep the choices under review.

5. FORMULARY GROUP DECISIONS DECEMBER 2021 – PUBLISHED – 31/12/2021

Members ratified the decisions of the December 2021 meeting as published. **FTEAM**

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6. NETFORMULARY/FORMULARY REVIEW

6.1. SBAR - TERIFLUNOMIDE PAEDIATRIC LICENCE EXTENSION

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

The Group considered the information regarding the paediatric licence extension for teriflunomide for the treatment of paediatric patients with relapsing remitting multiple sclerosis (RRMS).

Ms Doney confirmed that:

- teriflunomide, as the 14mg tablet, is already included on the formulary for adults with RRMS, in line with SMC 940/14 - as an alternative to treatment with interferon beta or glatiramer acetate. Teriflunomide is not expected to be used for the treatment of patients with highly active disease.
- the licence for teriflunomide has been extended to include paediatric patients aged 10 to <18 years
- paediatric dosing is weight-based [body weight >40 kg: 14mg once daily, ≤40 kg: 7mg once daily]
- the 7mg tablet has not been marketed in the UK yet
- the Paediatric Neurology Service look after this patient group, with treatment decisions discussed by a national multidisciplinary team. For older adolescents local adult neurology colleagues would be involved.
- the SMC advice for adults takes account of the benefits of a PAS that improves the cost-effectiveness of teriflunomide. The Formulary Team is awaiting confirmation that the PAS has been extended to include paediatric patients.
- patient numbers are expected to be very small

The Group accepted the restricted local need for teriflunomide for the treatment of paediatric patients aged 10 years to <18 years with RRMS in line with the formulary positioning for adults.
Acceptance is contingent upon confirmation that the PAS is extended to include paediatric patients.

SBAR - Teriflunomide 14mg film-coated tablets (Aubagio®) is routinely available in line with local guidance.
Indication under review: for the treatment of paediatric patients aged 10 years to <18 years with relapsing remitting multiple sclerosis.
Restriction: as an alternative to treatment with interferon beta or glatiramer acetate.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. The treatment should be initiated and supervised by a physician experienced in the management of multiple sclerosis. **FTEAM**

7. OTHER BUSINESS

None.

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2258 - ESKETAMINE (MAJOR DEPRESSIVE DISORDER)

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

The Group considered the request for esketamine in combination with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI), for adults with treatment-resistant Major Depressive Disorder, who have not responded to at least two different treatments with antidepressants in the current moderate to severe depressive episode.

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The Group noted:

- esketamine:
  - is a Schedule 2 Control Drug and is subject to safe custody, prescription and record keeping requirements
  - is available as a single-use nasal spray delivering 28mg per device
  - is intended to be self-administered by the patient, but this must be under the direct supervision of a healthcare professional so will require clinic attendance [both administration and post-administration observation should be carried out in an appropriate clinical setting]
  - [for this indication] dosing varies from one to three devices per administration with the frequency varying from twice a week during induction, to weekly or every two weeks during the maintenance phase
  - represents a new cost to the service, and will only be supplied from a clinic in Royal Cornhill Hospital
- the service plans to use esketamine nasal spray as an additional treatment option and has drafted a treatment algorithm to support its use
- the service plans to stop treatment at 6 months with the potential for another course to be considered if symptoms recur
- the service will need to factor in the additional resource requirements [time, staffing, clinic space] related to the introduction of esketamine, particularly with the different dosing frequencies and observation time required
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of esketamine nasal spray
- the highly variable cost implications due to the variable dose and frequency of administration
- that esketamine is not suitable for prescribing in Primary Care, and ScriptSwitch should be updated to reflect this **FD**
- that esketamine is also licensed as an acute short-term treatment for the rapid reduction of depressive symptoms which constitute a psychiatric emergency, but this indication will not be considered locally until SMC advice is issued

The Group accepted the restricted local need for esketamine in combination with a SSRI or SNRI, for adults with treatment-resistant Major Depressive Disorder, who have not responded to at least two different treatments with antidepressants in the current moderate to severe depressive episode, as outlined in SMC 2258.

SMC 2258 - Esketamine 28mg nasal spray, solution (Spravato®) ▼ is routinely available in line with national guidance (SMC 2258).
Indication under review: in combination with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI), for adults with treatment-resistant Major Depressive Disorder, who have not responded to at least two different treatments with antidepressants in the current moderate to severe depressive episode.
In a phase III study in adults (aged 18 to 64 years) with treatment resistant depression, esketamine plus newly initiated antidepressant significantly reduced the Montgomery-Åsberg Depression Rating Scale (MADRS) total score from baseline to week 4 compared with placebo plus newly initiated antidepressant. A significantly lower rate of relapse in patients who received esketamine plus antidepressant over placebo plus antidepressant was demonstrated in a further phase III study.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/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. The decision to prescribe Spravato® should be determined by a psychiatrist. Spravato® is intended to be self-

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administered by the patient under the direct supervision of a healthcare professional. A treatment session consists of nasal administration of Spravato® and a post-administration observation period. Both administration and post-administration observation of Spravato® should be carried out in an appropriate clinical setting. **FTEAM**

8.2. FG1SMC 2380 - PEMBROLIZUMAB (HODGKIN LYMPHOMA)

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

The Group considered the request for pembrolizumab as monotherapy for the treatment of adult and paediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option.

The Group noted that:

- pembrolizumab:
  - was previously accepted for use in a similar indication [SMC 1296/18], however use was restricted to adults that had failed to respond to brentuximab vedotin. The new licence moves pembrolizumab higher up the treatment pathway, ahead of brentuximab, and extends use to children and adolescents 3 years and older.
  - [for this indication] is given as an intravenous infusion as 200mg every 3 weeks or 400mg every 6 weeks for adults, and 2mg/kg every 3 weeks for paediatrics
  - [for this indication] is subject to a two-year clinical stopping rule
  - [for this indication] showed improved progression-free survival in KEYNOTE-204 [12.6 months for pembrolizumab versus 8.2 months for brentuximab]
- the service has significant experience using pembrolizumab for other indications
- cost offset is available from brentuximab as pembrolizumab will be moving up the treatment pathway in place of brentuximab
- patient numbers are expected to be small
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of pembrolizumab

The Group accepted the restricted local need for pembrolizumab as monotherapy for the treatment of adult and paediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma who have failed ASCT or following at least two prior therapies when ASCT is not a treatment option, as outlined in SMC 2380.

SMC 2380 - Pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®) is routinely available in line with national guidance (SMC 2380).
Indication under review: as monotherapy for the treatment of adult and paediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option.
Restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.
In a phase III study, pembrolizumab increased progression free survival compared with an antibody-drug conjugate medication in patient with relapsed/refractory classical Hodgkin lymphoma who were ineligible for or had relapsed after ASCT.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/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. Therapy must be initiated and supervised by specialist physicians experienced in the treatment of cancer. **FTEAM**

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8.3. FG1SMC 2384 - PONESIMOD (RELAPSING FORMS OF MULTIPLE SCLEROSIS)

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

The Group considered the request for ponesimod for the treatment of adults with RRMS with active disease defined by clinical or imaging features, suitable for or requesting an oral treatment.

The Group noted that:

- ponesimod:
  - is the second sphingosine 1-phosphate (S1P) receptor modulator [after ozanimod] accepted for use in NHS Scotland for RRMS
  - requires additional monitoring, including electrocardiogram (ECG) monitoring, for patients with pre-existing cardiac conditions
  - will be supplied via a homecare arrangement
- patient numbers are expected to be small
- ozanimod will remain the first-line S1P receptor modulator and the service would like ponesimod included on formulary as an alternative for patients that cannot tolerate ozanimod
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ponesimod

The Group accepted the restricted local need for ponesimod for the treatment of adults with RRMS with active disease defined by clinical or imaging features, suitable for or requesting an oral treatment, as outlined in SMC 2384.

SMC 2384 - Ponesimod titration pack, 20mg film-coated tablets (Ponvory®) ▼ is routinely available in line with national guidance (SMC 2384).
Indication under review: the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features, suitable for or requesting an oral treatment.
Ponesimod offers an additional treatment choice in the therapeutic class of sphingosine-1-phosphate receptor modulators.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) delivering the cost-effectiveness results upon which the decision was based, or a PAS/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 under the supervision of a physician experienced in the management of multiple sclerosis. FTEAM

8.4. FG1SMC 2337 - BARICITINIB (ATOPIC DERMATITIS)

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

The Group considered the request for baricitinib for the treatment of moderate to severe atopic dermatitis in adults who are candidates for systemic therapy who have failed at least one current systemic immunosuppressant due to intolerance, contraindication or inadequate disease control.

The Group noted:

- baricitinib:
  - is the first Janus Kinase (JAK) inhibitor to be licensed for the treatment of atopic dermatitis
  - is currently included on the formulary for rheumatoid arthritis
  - offers an oral treatment option with a different mechanism of action [to other agents for atopic dermatitis]
  - will be supplied via a homecare arrangement

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- [for this indication] has the potential to be a long-term treatment option and costs will be cumulative
- there may be some cost offset available from displacement of other agents
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of baricitinib

The Group accepted the restricted local need for baricitinib for the treatment of moderate to severe atopic dermatitis in adults who are candidates for systemic therapy who have failed at least one current systemic immunosuppressant due to intolerance, contraindication or inadequate disease control, as outlined in SMC 2337.

SMC 2337 - Baricitinib 2mg, 4mg film-coated tablets (Olumiant®) ▼ is routinely available in line with national guidance (SMC 2337).
Indication under review: for the treatment of moderate to severe atopic dermatitis in adults who are candidates for systemic therapy who have failed at least one current systemic immunosuppressant due to intolerance, contraindication or inadequate disease control.
Four phase III studies demonstrated superiority of baricitinib in improving signs and symptoms of atopic dermatitis when compared with placebo, as monotherapy or in combination with topical corticosteroids in patients with moderate to severe atopic dermatitis.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/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 the conditions for which baricitinib is indicated. **FTEAM**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED JANUARY 2022

The Group noted the SMC provisional advice issued January 2022.

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS – PUBLISHED JANUARY 2022

The Group noted the SMC advice published January 2022.

Following publication of the negative SMC recommendation for nivolumab (Opdivo®) SMC 2397, and the non-submission statement for eculizumab (Soliris®) SMC 2456, 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 2398 tucatinib (Tukysa®) ▼ (submission expected)
- SMC 2388 trastuzumab deruxtecan (Enhertu®) ▼ (submission expected)
- SMC 2403 tralokinumab (Adtralza®) ▼ (submission expected)
- SMC 2382 osimertinib (Tagrisso®) ▼
- SMC 2430 opicapone (Ongentys®) (clinicians not responded)
- SMC 2448 budesonide (Cortiment®) (submission expected)

Local advice for these medicines and indications will be included in the January 2022 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 SCOTTISH MEDICINES CONSORTIUM

None.

12. DOCUMENTS FOR INFORMATION

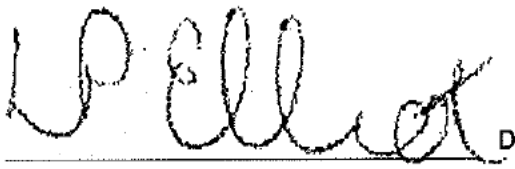
Item 12.1, Medwatch Newsletter Volume 2 Issue 8, was noted.

13. AOCB

None.

DATE OF NEXT MEETING

Tuesday 15 February 2022 starting at 14.30 via Microsoft Teams.

CHAIRMAN'S SIGNATURE  **DATE 15 FEBRUARY 2022**