NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 17 November 2020 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Ms M Galvin	
Ms F Doney	Professor J McLay	
Dr L Elliot (Chair)	Dr M Metcalfe	
Dr J Fitton	Dr A Sun	
Mrs L Harper		
Mrs L Montgomery		
Mrs K Neave		
Mr M Paterson		
Mr C Rore		
Mr R Sivewright		

IN ATTENDANCE
Dr Margaret MacLeod and Dr Elizabeth Visser, Consultant Neurologists for item 8.1
Ms Caitlin Wilkinson, Formulary Team administrator

OBSERVERS
Mrs Jenny Bevan, Formulary Team Specialist Pharmacy Technician
Ms Christine Hay, Formulary and Medicines Management Pharmacist

Note some items may be taken outwith the agenda running order.

ITEM	SUBJECT	ACTION
	The Chair welcomed members, opened the meeting and noted that a quorum was present.	
1.	**APOLOGIES**	
	Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 20 OCTOBER 2020**	
	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**
4.	**MATTERS ARISING**	
	4.1. DECISIONS TAKEN DURING TEMPORARY MEASURES	
	The Chair confirmed that there are no minutes of the Executive (decision-making) Group meetings to support the decisions taken during the interim governance arrangements (March to July 2020). Members were asked to review the Formulary Executive decision-making Group decision log and consider if additional information is required for any decisions, or if some items should be discussed at a future meeting. Feedback to be returned to the Formulary Team within the next two to three weeks.	**ALL**
3.	**PRESENTATION – FAMPRIDINE/SIPONIMOD IN MS**	
	The Chair welcomed Dr Margaret-Ann MacLeod and Dr Elizabeth Visser, Consultant Neurologists, to the meeting to discuss the management of multiple sclerosis (MS), including the introduction of two medicines recently accepted for use in NHS Scotland. Dr MacLeod provided the Group with an overview of the management of MS in NHS Grampian, before moving on to discuss fampridine and siponimod.	

Dr MacLeod reported that:

- she and Dr Visser have an interest in MS and do most of the prescribing for disease-modifying therapies, other than beta-interferons. However, there are too many people with MS for two Consultant Neurologists to manage, and all of the Consultant Neurologists share the management of people with MS.
- as people with MS become secondary progressive they move to management by the Neurorehabilitation service, with a number being shared between the two services
- in Aberdeen, and to some extent in Moray, there are dedicated MS rehabilitation services, with physiotherapists and occupational therapists that deal primarily with neurological conditions and MS. However, in some areas, the service is more scattered, and there may be nurses and/or Allied Health Professions (AHPs) who are not experienced in neurological conditions/MS, making assessments [for fampridine] more difficult.
- there are MS nurses located in Aberdeen, Moray, Orkney and Shetland
- MS is an inflammatory disease of the central nervous system [demyelination], and most patients at first have a relapsing-remitting course. As time goes on most people will develop progressive disease [axonal loss], however the course for each patient is entirely different and the timing of progression is variable.
- figures estimate that approximately half of people with MS will have secondary progressive MS by 15 - 20 years
- people with relapsing remitting MS are often on disease-modifying therapies and require regular review. As people come off disease-modifying therapies some move to the rehabilitation team, and some choose not to come back for review.
- NICE now recommends that people with MS should have a review at least once a year
- there are a small number of people with primary progressive MS, so progress from diagnosis and do not have relapses. It is not always clear-cut who has become secondary progressive or who is primary progressive.
- in progressive disease, people are not likely to have relapses but their disability gets worse. It is not possible to predict how the disease will affect an individual; some people have an aggressive course and others a much slower course with not much change from year to year. The course of disease progression will influence who is eligible for treatment(s).
- due to these uncertainties, it is difficult to accurately predict how many people with MS have secondary progressive MS
- a local database was created to track the number of people with MS. However, the services do not have the capacity to populate and maintain comprehensive information.
- the local database has a clear record of patients on disease-modifying therapies, but does not record EDSS [expanded disability status scale]
- in NHS Grampian ~ 60 new cases of MS are diagnosed per year, the majority will be relapsing remitting MS and a small proportion will be secondary progressive or primary progressive MS
- in relapsing remitting MS, there are a number of disease-modifying therapies that can be used first-line, and for patients that continue to have relapses move to second-line agents. Siponimod would be an alternative disease-modifying therapy to interferon beta-1b in secondary progressive MS with active relapses.
- there are an array of symptomatic treatment options. Fampridine is a symptomatic treatment option that could be used for the improvement of walking in adult patients with any form of MS.

Fampridine

- fampridine is accepted for use in NHS Scotland for the improvement of walking in adult patients with MS (any category) with an EDSS of 4 to 7
- EDSS is a way of measuring how much a person is affected by their MS. The scale runs from zero to 10. EDSS 1 is minimal signs of disability [very small sign that one function is not normal]. As people move through the scale their walking distance reduces and they need more aids to help them walk. [EDSS 4 implies impaired

walking - significant disability but able to walk without an aid or rest for 500 meters, and EDSS 7 is essentially restricted to a wheelchair - but active all day, can't walk more than 5 metres even with an aid, wheels self in chair, transfers alone].

- EDSS is a widely used but flawed scale, there are recognised problems but a suitable alternative has not been developed. EDSS considers walking distance and lower limb disability, it does not take account of problems with upper limb mobility or cognition, which are concerns for people with MS.
- fampridine is:
  - a selective potassium channel blocker that stimulates the damaged nerves [which in turn stimulate the muscles] to improve walking speed or distance
  - an oral tablet with a number of side-effects related to its stimulant effect on the nervous system, a number of people have to stop treatment due to side-effects
  - does not slow progression, it might improve walking distance and/or walking speed
  - requires six-monthly renal function tests
- there are clear guidelines for the assessment of fampridine treatment; the Timed 25 Foot Walk (T25FW) or Twelve Item Multiple Sclerosis Walking Scale (MSWS-12)
- assessment is required before treatment initiation, and again after two to four weeks of treatment. People need to show an improvement in either or both scales. For those that continue treatment if there is a decline in walking ability, fampridine treatment is interrupted and reassessed.
- fampridine is not slowing progression, it is potentially improving function. People will require ongoing clinic assessment after the initial decision to initiate and continue treatment.
- all people with EDSS 4 – 7 will be assessed, but the expectation is that only a small proportion of people with benefit
- some people with MS will be under the care of their GP, and these will now be added to the Neurology/Neurorehabilitation service caseload
- some people with progressive MS may have been followed up every year or two, and the use of fampridine will increase the frequency of visits to the specialist services
- the additional workload related to the introduction of fampridine cannot be absorbed into the existing service

Siponimod

- siponimod is accepted for use within NHS Scotland for the treatment of adults with secondary progressive MS with active disease evidenced by relapses or imaging features of inflammatory activity [on an MRI scan]
- the suggestion is that siponimod is associated with a reduction in disability progression confirmed after three months in secondary progressive MS, evidence comes from the EXPAND trial
- many people with secondary progressive MS do not have relapses, and for those that do there is a possibility that at three months people may not have fully recovered from the relapse, so assessing progression at three months may be problematic
- current understanding is that relapses are caused by demyelimation or inflammation, whereas progression to a large extent is caused by loss of nerve cells [axonal-loss]
- siponimod:
  - is a sphingosine-1-phosphate receptor modulator
  - is similar to fingolimod, it reduces recirculation of T-cells back into the CNS [anti-inflammatory action]
  - has a similar effect on the heart to fingolimod, it causes a transient reduction in heart rate and atrioventricular conduction on treatment initiation. Treatment has to be initiated slowly with a 5-day titration pack. If maintenance treatment is interrupted for four or more consecutive daily doses, siponimod needs to be re-initiated with a new titration pack.
  - requires CYP2CP metaboliser status to be established before initiating treatment; patients homozygous for CYP2C9*3 should not be treated with siponimod, as use of siponimod in these patients results in substantially elevated siponimod plasma

levels. If heterozygous the maintenance dose is reduced.

- side-effects are similar to fingolimod and other disease-modifying therapies, and include headache, hypertension, infection, seizures
- the inclusion criteria in the trial included EDSS 3 to 6.5, and evidence of active disease
- baseline screening is similar to other disease-modifying therapies
- everyone [on siponimod] will require regular ongoing monitoring [full blood count, liver function tests and screening for macular oedema and cutaneous neoplasms], and regular MRI scans [looking for aggressive new disease activity and also as a baseline for progressive multifocal leukoencephalopathy]. These people would previously not have required 6-monthly review or an annual MRI scan.
- there are questions about who will be eligible for treatment. It is worth noting that if people have very active progression in their MS over six months or more without relapses, then this is a person that the services would be keen to try something like siponimod. Also, people that are rapidly losing upper limb function/cognition are clearly becoming more disabled but this would not be picked up on EDSS.
- it is not clear how the CYP2CP genotype will be assessed; awaiting advice from national genetics meeting
- many people with secondary progressive MS will require discussion, in clinic, even if they are not eligible for treatment [with siponimod], and there may be others on alternative disease-modifying therapies that may wish to switch treatment
- locally, prescribing of disease-modifying therapies is in line with the Association of British Neurologists guidelines

In response to questions, Dr MacLeod and Dr Visser confirmed that:

- the introduction of fampridine and siponimod will require additional resource(s) to be incorporated into the existing service(s), e.g. MS nurses/AHPs with experience in the nuanced management required for these patients with complex long-term needs; increased monitoring visits, additional MRI scans and genetic testing for CYP2C9 metaboliser status
- prescribing cannot start without additional resource(s) being in place, and the service must be safe, sustainable and equitable
- assessments cannot be performed remotely, patients will have to come into the unit/service because of the safety aspects of assessment/management (people may have limited mobility)
- clinic capacity has reduced during the COVID-19 pandemic
- blood monitoring for disease-modifying therapies is managed by the service
- whether people with MS are eligible [or not] for treatment they will require education/discussion about the new treatment(s)
- introduction will involve assessment of a large number of patients, even if only a small proportion will ultimately initiate and continue on treatment
- there are uncertainties about how to manage the introduction of both agents

As General Practice manages a group of people with MS, members considered that there is an educational requirement for Primary Care. When the service is in a position to initiate treatment, the Group supported provision of information about the new treatments and advice regarding which people with MS should be referred back to neurological services for consideration of treatment. **NEURO**

The Chair thanked Dr Macleod and Dr Visser for the informative presentation and discussion. Dr Macleod and Dr Visser left the meeting before decision-making.

The Group recognised that the introduction of fampridine and siponimod will have significant service implications for the Neurology, Neurorehabilitation, nursing, AHP and imaging services, and currently there is insufficient capacity to commence prescribing of these medicines in a safe and sustainable manner.

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8.1 FG1SMC 2253 - FAMPRIDINE (MULTIPLE SCLEROSIS)

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

A request for siponimod is awaited so the Group moved to consider the request for fampridine for the improvement of walking in adults with MS with EDSS 4 to 7.

The Group noted that:

- fampridine:
  - is a symptomatic treatment that will be added to current therapy
  - requires initial and ongoing monitoring, and this will entail additional appointments with Neurologists, MS nurses, AHPs etc. Many of these people with MS would previously not have required regular appointments with the service(s).
- the ARI Neurology department cannot take on all of the assessments for fampridine
- the introduction of fampridine will create a significant pressure on the service(s), particularly initially as a large group of people are assessed for treatment. After this, a small cohort of people [incident population] will be eligible for assessment.
- assessments cannot be undertaken remotely, and appointment capacity has reduced during COVID-19
- the gaps in the data and the difficulties accurately estimating the potential population
- EDSS does not take account of upper limb disability [arms, hands and fingers] or cognition, which are concerns for people with MS
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of fampridine, however the PAS is not currently available to Primary Care
- NICE Clinical Guideline [CG186] Multiple sclerosis in adults: management - does not currently recommend fampridine "*1.5.10 Do not use fampridine to treat lack of mobility in people with MS because it is not a cost effective treatment*". The guideline is currently under review.

The Group acknowledged that MS is a chronic progressive condition, and fampridine is a symptomatic treatment option. Many people with MS will be assessed but not all will be eligible for treatment. Of those eligible, a small proportion might respond to treatment and response may not be maintained in the long-term.

The Group agreed that:

- additional resource and local implementation plans are required to allow the safe and sustainable introduction of fampridine
- the Neurology service should submit a paper to the Directors of Nursing and AHPs outlining the requirements for the introduction of fampridine
- fampridine is not suitable for prescribing in Primary Care

The Group accepted that there is a restricted local need for fampridine, however introduction will have significant service implications and represents a risk to service delivery.

SMC 2253 - Fampridine 10mg prolonged-release tablet (Fampyra®) is not routinely available as local implementation plans are being developed.
Indication under review: for the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS [expanded disability status scale] 4-7). In double-blind phase III studies fampridine, compared with placebo, improved walking ability in adults with multiple sclerosis and walking impairment. 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. Not routinely available as local implementation plans are being developed. FTEAM

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4. MATTERS ARISING

4.2. ACTION LOG

The November 2020 Action log was noted.
No additional items were identified that should have been included on the agenda.

4.3. ANDEXANET ALFA (SBAR)

There were no declarations of interest recorded in relation to this product, or the direct oral anticoagulants (DOACs).

Ms Doney confirmed that the SBAR was submitted for and discussed at the November meetings of the Grampian Area Drug and Therapeutics Committee (GADTC) and Primary Care Prescribing Group (PCPG).

Ms Doney reported that the Groups have advised that:

- in the absence of a licensed reversal agent for edoxaban and limited evidence, to date, published to support a position to be taken on off-label use at a population level
- edoxaban is to be replaced as the first-line direct oral anticoagulant (DOAC) for new patients with apixaban and/or rivaroxaban
- a request has been made for the Formulary Group to publish advice on the clinical appropriateness of apixaban and rivaroxaban — **FTEAM**
- existing patients, whose management is stable on edoxaban, can generally stay on it whilst we await the trial evidence around off-label use of andexanet alfa in this group of patients. Whilst there will be no instruction for mass switch any patient requesting a switch should be supported to make the appropriate treatment decision for them as an individual. Likewise, GPs should continue to exert clinical judgement where they think a switch is necessary.
- the Medicines Management Team will issue information advising of the change of first-line DOAC, and the reasoning behind the decision — **MMT**
- evidence for the use of andexanet alfa for edoxaban reversal will be monitored — **FTEAM**
- it is important to monitor how other Health Boards in Scotland respond

Mr Rore confirmed that another drug, ciraparantag, is under investigation as an antidote to edoxaban. Estimated to be available in 2023.

Ms Doney confirmed that data from the andexanet alfa post-marketing studies are expected by mid-2023, and the change in first-line DOAC will have a significant financial impact.

4.4. NCMAG SBAR

Ms Doney confirmed the SBAR was discussed at the November GADTC meeting.

The GADTC was minded to support the National Cancer Medicines Advisory Group (NCMAG) framework subject to clarification of the statement within the framework "*the national group has delegated responsibility for decisions"*.

Feedback from the GADTC is awaited. — **GADTC**

4.5. FORMULARY GROUP REPORT SUBMITTED TO NOVEMBER GADTC

The Group noted the Formulary Group Annual Report 2019-2020.

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4.6. USTEKINUMAB FOR ULCERATIVE COLITIS (UPDATE)

Ms Doney reported that ustekinumab for the treatment of ulcerative colitis (SMC 2250) was accepted to formulary at the October 2020 meeting, and the service has answered the questions from the submission. The responses were sent out via email before the meeting and do not alter the outcome of the October meeting.

Ms Doney confirmed that:

- there is a local database for patients receiving biologic agents for gastrointestinal indications (including patients from Orkney and Shetland)
- golimumab has little use locally, but will remain on formulary meantime

5. FORMULARY GROUP DECISIONS OCTOBER 2020 – PUBLISHED – 2 NOVEMBER 2020

5.1. FORMULARY GROUP DECISIONS OCTOBER 2020

Members ratified the decisions of the October 2020 meeting as published. **FTEAM**

6. NETFORMULARY/FORMULARY REVIEW

6.1. VITAMIN B12 SBAR

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

The Group reviewed the information submitted regarding the marketing of a newly licensed cyanocobalamin 1mg tablet, Orobalin®.

The Group noted that:

- at the start of the pandemic, the Grampian Medicines Information (MI) department issued information regarding prescribing vitamin B12 during the COVID-19 pandemic, and advised that oral vitamin B12 at a dose of 1mg daily was an alternative to intramuscular vitamin B12
- the UKMI document '*Oral vitamin B12 – what are the prescribing considerations and what formulations are available?'* advises "*Do not prescribe oral vitamin B12 for patients presenting with neurological involvement; in these cases, seek urgent advice from a haematologist. IM hydroxocobalamin should be given if this advice is not immediately available*."
- patients are beginning to find their way back into practices' for routine injections such as vitamin B12 injections
- the [licensed] oral 1mg preparation is more expensive than hydroxocobalamin injection, even taking into consideration the cost of nursing/healthcare support worker time for administration of the injection
- the availability of an oral 1mg preparation provides a particular advantage during COVID-19, and formulary inclusion could be a temporary arrangement with review in 12 to 18 months
- generic prescribing is supported and systems should be used to direct colleagues, including Community Pharmacists, to the licensed 1mg product

Mr Rore confirmed that he would liaise with colleagues in haematology to update the MI document, and confirm if oral vitamin B12 is appropriate for acute treatment and prophylaxis. **CR**

The Chair requested the local MI document is updated in line with haematology feedback and circulated to General Practice when available. **MI**

The Group agreed that availability of a licensed oral vitamin B12 preparation would support strategies to minimise invasive interactions with patients during COVID-19, and a licensed preparation is preferred to use of an unlicensed preparation.

The Group accepted the restricted local need for cyanocobalamin 1mg tablets as an

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alternative treatment option for patients with non-diet related vitamin B12 deficiency. The decision is subject to review in 12 to 18 months. **FTEAM**

Cyanocobalamin 1mg film-coated tablets (Orobalin®) is routinely available in line with local guidance.
Indication under review:

- **for non-diet related vitamin B12 deficiency**

It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care. **FTEAM**

7. OTHER BUSINESS

7.1. BIOSIMILAR MEDICINES: A NATIONAL PRESCRIBING FRAMEWORK (2018)

Ms Doney confirmed that the Area Drug and Therapeutics Committee Collaborative (ADTC Collaborative) has requested that local ADTCs review the 'Biosimilar medicines: A national prescribing framework' to consider if it remains fit for purpose, requires update or withdrawal.

Members were asked to review the framework document and feedback any comments within the next few weeks. **ALL**

8. NEW PRODUCT REQUESTS

8.2. FG1SMC 2266 - CAPLACIZUMAB (ACQUIRED THROMBOTIC THROMBOCYTOPENIC PURPURA (ATTP))

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

The Group considered the request for caplacizumab for the treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (TTP), in conjunction with plasma exchange and immunosuppression.

The Chair confirmed that acquired TTP is a rare autoimmune condition. During an episode of acquired TTP, blood clots form in small blood vessels and the patient has a low platelet count. Acquired TTP can be acutely life-threatening, and in the longer term may cause cognitive deficits, depression, hypertension and a shortened life expectancy.

The Group noted:

- caplacizumab:
  - is the first medicine licensed for acquired TTP
  - is administered as an intravenous injection [10mg] prior to plasma exchange, and then as a 10mg daily subcutaneous injection after completion of each plasma exchange for the duration of daily plasma exchange treatment, followed by daily subcutaneous injection [10mg] for 30 days after stopping daily plasma exchange treatment. In the clinical development program, caplacizumab has been administered daily for up to 65 days. No data on re-treatment with caplacizumab is available.
  - represents a new cost as it is added to current standard of care (plasma exchange and immunosuppression)
  - will be used in severe or refractory cases
  - is an expensive treatment that offers improved outcomes to patients with a life-threatening condition [returned platelet counts to normal faster than placebo plus standard of care, and secondary outcomes were improved – fewer days of plasma exchange (median duration 5 days versus 7 days), days in ICU (median duration 3 days versus 5 days), hospital stay (median duration 9 days versus 12 days)]
- was accepted, following a full submission reviewed by the SMC executive, for the treatment of adults experiencing an episode of acquired TTP in conjunction with plasma exchange and immunosuppression

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- June 2020, the indication was extended to include adolescents 12 years of age and older weighing at least 40kg
- paediatric licence extensions are outwith remit for SMC
- the Haematologists have confirmed that it would be reasonable to extend the local request to include adolescents aged 12 years to <18 years
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of caplacizumab, and the PAS has been extended to include adolescents 12 years to <18 years

The Group accepted the restricted local need for caplacizumab for the treatment of adults and adolescents aged 12 to <18 years of age experiencing an episode of acquired TTP, in conjunction with plasma exchange and immunosuppression.

SMC 2266 - Caplacizumab 10mg powder and solvent for solution for injection (Cablivi®)▼ is routinely available in line with national guidance (SMC 2266).
Indication under review: treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression.
Caplacizumab, compared with placebo, decreased the time to platelet count response and reduced the risk of thrombotic thrombocytopenic purpura recurrence in adults receiving plasma exchange and immunosuppression for aTTP.
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 and supervised by physicians experienced in the management of patients with thrombotic microangiopathies. **FTEAM**

Caplacizumab 10mg powder and solvent for solution for injection (Cablivi®)▼ is routinely available in line with local guidance.
Indication under review: treatment of adolescents aged 12 to <18 years of age weighing at least 40kg experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression.
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 physicians experienced in the management of patients with thrombotic microangiopathies. **FTEAM**

8.3. FG1SMC 2272 - BROLUCIZUMAB (NEOVASCULAR (WET) AGE-RELATED MACULAR DEGENERATION (AMD))

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

The Group considered the request for brolucizumab for the treatment of adults with neovascular (wet) age-related macular degeneration (AMD).

The Chair confirmed that neovascular AMD is the leading cause of severe vision loss worldwide, and a proportion of people will progress to blindness in two years without treatment. Increasing age is a risk factor for neovascular AMD, therefore disease prevalence and demand for treatment will rise with an ageing population.

The Group noted:

- September 2020, following a full submission assessed through an amended process used during the COVID-19 pandemic, brolucizumab was accepted by SMC for the treatment of neovascular wet AMD

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- brolucizumab:
  - is the third intravitreal anti-VEGF agent licensed for wet AMD
  - has no requirement for monitoring between injections
  - offers the potential for extended dosing intervals, 8 to 12-weekly dosing interval, which would be beneficial for patients and service capacity particularly during the COVID-19 pandemic
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of brolucizumab
- the other anti-VEGF therapies are also subject to confidential pricing arrangements
- the trial does not reflect potential use in clinical practice, as brolucizumab may be offered to treatment-experienced patients, and aflibercept is also licensed as a 'treat and extend' regimen
- adverse events are in line with other intravitreal anti-VEGF therapies, with the exception of a confirmed safety signal of [rare adverse events of] retinal vasculitis and/or retinal vascular occlusion
- the service has confirmed that if the injection is delivered by someone who is not medically qualified, there is cover in place to manage any ophthalmological or medical complications

The Group accepted the restricted local need for brolucizumab, for the treatment of adults with neovascular wet AMD, as outlined in SMC 2272.

SMC 2272 - Brolucizumab 120mg/mL solution for injection in pre-filled syringe (Beovu®)▼ is routinely available in line with national guidance (SMC 2272). Indication under review: in adults for the treatment of neovascular (wet) age-related macular degeneration (AMD).
Non-inferiority of brolucizumab versus another anti-vascular endothelial growth factor medicine was demonstrated for mean change in best corrected visual acuity from baseline to week 48 in two phase III studies in patients with neovascular AMD. 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. **FTEAM**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – NOVEMBER 2020

The Group noted the SMC provisional advice issued November 2020.

If the negative SMC recommendation is published next month, this medicine will not be included on the formulary for the indication in question.

SMC 2307 - MEXILETINE (NAMUSCLA®)

Ms Davie highlighted the provisional advice for mexiletine (Namuscla®), for the symptomatic treatment of myontonia in adult patients with non-dystrophic myotonic disorders, and queried if there is any prescribing in Primary Care [for this indication]. Ms Doney will check if the PAS is available to Primary Care. **FD**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS – NOVEMBER 2020

The Group noted the SMC advice published November 2020.

Following publication of the negative SMC recommendation for patiromer (Veltassa®)▼ SMC 2264 this medicine will not be included on the Grampian Joint Formulary for the indication in question.

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The following SMC accepted medicines have not been processed within a 60-day timescale:

- SMC 2283 trabectedin (Yondelis®) (submission expected)
- SMC 2279 atezolizumab (Tecentriq®) ▼ (submission expected)
- SMC 2267 atezolizumab (Tecentriq®) ▼ (submission expected)
- SMC 2297 darolutamide (Nubeqa®) ▼ (submission expected)
- SMC 2280 romosozumab (Evenity®) ▼ (submission expected)
- SMC 2298 trastuzumab emstansine (Kadcyla®) (submission expected)

Local advice for these medicines and indications will be included in the November 2020 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

ULTRA-ORPHAN MEDICINES ASSESSMENT REPORTS (UMAR)

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

The Chair highlighted the SMC initial assessment report published for volanesorsen (Waylivra®). Volanesorsen is a medicine licensed for a very rare disease. It has been validated as meeting SMC ultra-orphan (UO) criteria and will be made available through the NHS in Scotland for up to three years [for the indication in question] while evidence on its effectiveness is generated – *the Scottish Government (SG) ultra-orphan pathway*.

Medicines accessed via the SG ultra-orphan pathway are considered outwith remit for the Formulary Group, and are classified as 'non-formulary'.

SMC 2299 - Volanesorsen 285mg solution for injection in prefilled syringe (Waylivra®) ▼ is not routinely available in NHS Grampian.
Indication under review: as an adjunct to diet in adult patients with genetically confirmed familial chylomicronaemia syndrome (FCS) and at high risk for pancreatitis, in whom response to diet and triglyceride lowering therapy has been inadequate.
Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI). **FTEAM**

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM - NOVEMBER 2020

None

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update October 2020), 12.2, 12.3 (Medicine Guidelines and Policies Group minutes February and June 2020), 12.4, 12.5 (Antimicrobial Management Team minutes July 2020 and September 2020), 12.6 (Grampian Area Drug and Therapeutics Committee minute September 2020) and 12.7 (MedWatch newsletter September 2020) were noted.

13. AOCB

MEMBERS UPDATE

Mr Rore reported that he tendered his resignation from NHS Grampian, and his last Formulary Group meeting will be February 2021.

Mrs L Harper confirmed she will retire from NHS Grampian at the end of the year and her last Formulary Group meeting will be December.

ITEM	SUBJECT	ACTION

DATE OF NEXT MEETING

Tuesday 15 December 2020 starting at 14.30 via Microsoft Teams.

CHAIR'S SIGNATURE L P Elliot **DATE** **15 DECEMBER 2020**