NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 21 December 2021 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms L Cameron	Dr J Fitton	
Ms A Davie	Mrs G McKerron	
Ms F Doney	Mrs S O'Beirne	
Dr L Elliot		
Ms M Galvin		
Professor J McLay (Chairman)		
Dr M Metcalfe (to item 8.5)		
Mrs L Montgomery (from item 3)		
Mrs K Neave		
Dr J Newmark		
Mr M Paterson		
Mr R Sivewright		

IN ATTENDANCE
Ms Christine Hay, Formulary and Medicines Management Pharmacist
Mrs Anne Rembisz, Formulary Team administrator

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	The Chairman 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 16 NOVEMBER 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.	**DISCUSSION – ADRENALINE AUTO INJECTORS** Members noted the content of the Commission on Human Medicines' Public Assessment Report "Adrenaline Auto-injector Expert Working Group: Recommendations to support the effective and safe use of adrenaline auto-injectors". Dr Rick Herriot, Consultant Immunologist, attended the meeting to answer questions from members. Dr Herriot confirmed that: • the prescribing of adrenaline auto-injectors for the treatment of severe anaphylactic reactions is appropriate and practical, however the diagnosis of severe anaphylactic reactions is sometimes not correct • there is not a protocol for the prescribing of adrenaline auto-injectors but there are general principles that immunologists/doctors use for prescribing • the dosage of adrenaline [for adults] varies between auto-injectors used in the community [300micrograms] and adrenaline dosage used in a hospital environment [500micrograms] • the pharmacokinetic data is confusing, but real world experience is that 300micrograms administered by an auto-injector to a person without confounding cofactors is very effective, i.e., 300micrograms from Epipen® or Jext® is an effective dose in the vast majority of circumstances as long as proper pre- and post-postural	

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recommendations are followed
- we do not know how often people use two auto-injectors for an anaphylactic reaction, or how many people carry two auto-injectors
- we do not know if the incidence is increasing as there is not a database of anaphylactic reactions/anaphylaxis, however allergies are very common and there is an increasing recognition of allergy
- Emerade® is rarely prescribed locally but there are some circumstances, i.e., body size or patient already established on Emerade®, where formulary inclusion would be warranted

Dr Herriot offered to summarise the circumstances in which adrenaline auto-injectors should be prescribed by practitioners and send them for members to review. **RH**

The Chairman thanked Dr Herriot for attending the meeting, and Dr Herriot left the meeting.

The Group agreed that:
- there is a restricted local need for Emerade®, and Ms Doney will provide a summary for decision-making at a future meeting **FD**
- the Public Assessment Report includes several important pieces of advice that should be taken forward locally, including some key patient safety messages **ALL/LC**

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**

5. FORMULARY GROUP DECISIONS NOVEMBER 2021 – PUBLISHED – 26/11/2021

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

6. NETFORMULARY/FORMULARY REVIEW

None.

7. OTHER BUSINESS

7.1. NATIONAL CANCER MEDICINES ADVISORY GROUP (NCMAG) UPDATE

Ms Galvin provided the Group with an update on the work of the COVID 19 National Cancer Medicines Advisory Group (NCMAG).

Ms Galvin confirmed that:
- April 2020, as part of COVID 19 response strategy, the Scottish Government Health Department issued interim governance arrangements for cancer medicines. These arrangements are led by the COVID 19 NCMAG which provides oversight of a 'Once for Scotland' approach to proposed interim changes to adult Systemic Anti-Cancer Therapy (SACT) practice.
- 29 proposals for interim use of cancer medicines have been considered, and 19 supported. Five have subsequently been withdrawn (four of these following SMC accepted recommendations).
- current COVID 19 NCMAG published advice is valid until the end of March 2022
- COVID 19 NCMAG advice is hosted on the West of Scotland Cancer Network (WoSCAN) intranet site
- currently NCMAG is not tasked with considering budgetary implications, however this

may change in the future as the Scottish Government has now committed substantive funding for a "business as usual" NCMAG to continue through and beyond COVID

NCMAG026, APIXABAN FOR THE PROPHYLAXIS OF VENOUS THROMBOEMBOLISM (VTE) IN ADULTS WITH MULTIPLE MYELOMA TREATED WITH IMMUNOMODULATORY DRUGS THALIDOMIDE, LENALIDOMIDE AND POMALIDOMIDE IN COMBINATION REGIMENS

Ms Galvin reported that:

- the local specialists would like to have apixaban considered for formulary inclusion in line with NCMAG026 as currently it is only accepted under the NCMAG umbrella. The advice is likely to be withdrawn after March 2022 because it is included on other Health Board formularies and available for use in other cancer networks [South East Scotland Cancer Network (SCAN) and WoSCAN].
- patient numbers are difficult to estimate but will be small, as use is limited to patients that cannot self-inject or do not have a household member that can administer injections

The Group discussed the possible formulary inclusion of apixaban for the prophylaxis of venous thromboembolism (VTE) in adults with multiple myeloma treated with immunomodulatory drugs thalidomide, lenalidomide, and pomalidomide in combination regimens, as outlined in NCMAG026.

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

The Group noted:

- apixaban, for this indication:
  - is off-label use, and will only be initiated on the advice of a specialist, patients will remain under the care of the specialist service [patients are reviewed every 4-8 weeks including regular blood monitoring]
  - will be used in a minority of patients, as prescribing will be restricted to those who cannot self-administer or do not have a household member that can administer dalteparin injections
- clear communication with colleagues in Primary Care is required
- administration of dalteparin injections by healthcare workers would require daily patient attendance at a clinical setting or daily visits by a healthcare worker to the patient's home
- the specialist service would like routine access to apixaban in line with NCMAG026 beyond March 2022 when this advice is likely to be withdrawn
- in the context of COVID-19:
  - the patient group is at increased risk of contracting COVID-19 through daily close contact with a person from outside their household
  - apixaban is an oral therapy that, as an alternative to daily subcutaneous injection, will significantly reduce contact time with those from other households
- apixaban is a widely established medicine, that will be used in a small minority of people

The Group accepted the restricted local need for the off-label use of apixaban as outlined in NCMAG026, without the requirement for a full submission.

NCMAG026 - Apixaban 2.5mg film-coated tablets (Eliquis®) is routinely available in line with local guidance.
Indication under review: [off-label] for the prophylaxis of venous thromboembolism (VTE) in multiple myeloma patients treated with immunomodulatory drugs thalidomide, lenalidomide, and pomalidomide in combination regimens.
Restriction: for use only in adults who would otherwise require administration of low molecular weight heparin by a person outside of their household.

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	It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist.	**FTEAM**

8. NEW PRODUCT REQUESTS

8.1. FG1 442/21 - ELTROMBOPAG OLAMINE (APLASTIC ANAEMIA)

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

The Group considered the request for eltrombopag olamine for the treatment of adults with acquired severe aplastic anaemia who are either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation.

The Group noted:

- eltrombopag:
  - is licensed for the requested indication but is not recommended by SMC based on a non-submission from the manufacturer, SMC 1164/16 (May 2016)
  - is included in the British Haematology guidelines '*Guidelines for the diagnosis and management of adult aplastic anaemia'* published November 2015
- patient numbers will be very small, and patients are currently receiving treatment with eltrombopag for this indication through the individual patient PACS process
- dosing is based on haematological response and the service has defined response criteria
- treatment is stopped if there is no response after 16 weeks, and if patients relapse on treatment
- treatment with eltrombopag will be used instead of repeat anti-thymocyte globulin (ATG). Eltrombopag is preferred as ATG is toxic, requires an in-patient stay, has a high failure rate and is predicted to increase the risk of severe COVID-19 disease as it is very immunosuppressive.
- eltrombopag is also used for the treatment of immune thrombocytopenia (ITP) and the service has significant experience prescribing eltrombopag. All patients would be assessed by a Consultant Haematologist and treatment would only be initiated by a Consultant.

The Group accepted the restricted local need for eltrombopag olamine for the treatment of adults with acquired severe aplastic anaemia who are either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation.

FG1 442/21 - Eltrombopag olamine 25mg, 50mg, 75mg film-coated tablets, 25mg powder for oral suspension (Revolade®) is routinely available in line with local guidance.
Indication under review: for the treatment of adults with acquired severe aplastic anaemia who are either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated by and remain under the supervision of a physician who is experienced in the treatment of haematological diseases and its complications. **FTEAM**

8.2. FG1SMC 2345 - AVATROMBOPAG (CHRONIC IMMUNE THROMBOCYTOPENIA (ITP))

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

The Group considered the request for avatrombopag for the treatment of primary chronic ITP in adults with severe symptomatic ITP or a high risk of bleeding who are refractory to

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other treatments (e.g. corticosteroids or immunoglobulins).

The Group noted that:

- avatrombopag:
  - is the third thrombopoietin (TPO) receptor agonist on the formulary
  - is currently included on the formulary for the treatment of severe thrombocytopenia in adults with chronic liver disease who are scheduled to undergo an invasive procedure (SMC 2296)
  - [for this indication] meets SMC orphan equivalent criteria, and was accepted for restricted use in NHS Scotland following the output from the PACE process and application of the appropriate SMC modifiers
  - is an oral treatment option, that is not associated with hepatotoxicity
- patient numbers will be very small
- the daily dose is based on the patient's platelet count, and the lowest dose should be used to achieve and maintain a platelet count ≥50 x 10^9/L
- if patients do not respond after 8 weeks treatment, avatrombopag will be discontinued
- in the trial, the median duration of exposure in the avatrombopag group was 26 weeks but the service stated that treatment could continue long-term
- some patients may have a trial off treatment after 6 months and remain off therapy if platelets are sustained >50 x10^9/L
- the service would prefer avatrombopag for some patient groups as oral administration means patients would not have to attend a clinical setting for subcutaneous injections
- cost offset is available as avatrombopag will be used in preference to the other TPO receptor agonists
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of avatrombopag

Members queried if three TPO receptor agonists are required on formulary, and if there would be a preferred agent.
Ms Doney will check the licensed indications of the three TPO receptor agonists. **FD**
Ms Galvin will clarify if three TPOs are required on the formulary and if there would be a preferred agent. **MG**

The Group accepted the restricted local need for avatrombopag for the treatment of primary chronic ITP, as outlined in SMC 2345.

SMC 2345 - Avatrombopag 20mg film-coated tablets (Doptelet®) ▼ is routinely available in line with national guidance (SMC 2345).
Indication under review: treatment of primary chronic immune thrombocytopenia (ITP) in adults who are refractory to other treatments (e.g. corticosteroids or immunoglobulins).
Restriction: to use in patients with severe symptomatic ITP or a high risk of bleeding.
In a phase III study, avatrombopag was more effective than placebo in raising and maintaining platelet counts at (or above) a minimum target level in previously-treated patients with ITP.
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 us equivalent or lower.
This advice takes account of the views from a Patients 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 by and remain under the supervision of a physician who is experienced in the treatment of haematological diseases. Avatrombopag should be taken at the same time of day (e.g. in the morning or evening) with food, including when taking the dose less frequently than once daily. **FTEAM**

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8.3. FG1SMC 2313 - GALCANEZUMAB (MIGRAINE)

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

The Group considered the request for galcanezumab for the prophylaxis of chronic and high frequency episodic migraine.

The Group noted that:

- galcanezumab
  - is the third calcitonin gene-related peptide (CGRP) antagonist licensed in the UK for the prophylaxis of chronic migraine, and the second licensed for episodic migraine [erenumab is not licensed for episodic migraine]
  - [like the other CGRP agonists] will be supplied via a homecare arrangement
  - is administered monthly as a subcutaneous injection
- response will be assessed at three months, and treatment will only be continued for responders
- treatment will be stopped at 12 months if a patient has an excellent response (reverts to low frequency episodic migraine)
- patient numbers are expected to be small
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of galcanezumab
- there are differences between the three CGRP antagonists in terms of licensing and side-effects, and at this time the service wishes to include all three on formulary

The Group accepted the restricted local need for galcanezumab for the prophylaxis of chronic and high frequency episodic migraine, as requested by the Headache Service.

SMC 2313 - Galcanezumab 120mg solution for injection in prefilled pen (Emgality®) ▼ is routinely available in line with local guidance.
Indication under review: for the prophylaxis of migraine in adults with:
1) chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine)
2) high frequency episodic migraine (headaches on 10 to 15 days per month)
Restriction: adults whose condition has failed to respond to ≥ 3 prior oral prophylactic treatments.
Selection of appropriate patients and provision of galcanezumab is limited to the NHS Grampian Headache Service.
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 migraine. **FTEAM**

8.4. FG1SMC 2376 – CABOTEGRAVIR INJECTION AND RILPIVIRINE INJECTION (HIV)

There were no declarations of interest recorded in relation to these products.

The Group considered the request for cabotegravir prolonged-release injection (Vocabria®) in combination with rilpivirine prolonged-release injection (Rekambys®), for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) class.

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The Group noted that:

- this is the first long-acting antiretroviral therapy regimen
- dosing with cabotegravir and rilpivirine consists of an oral lead-in phase, 30mg oral cabotegravir and 25mg oral rilpivirine once daily for one month, followed by intramuscular injections of 600mg cabotegravir and 900mg rilpivirine in months two and three before moving to two-monthly injections
- injections can be given up to seven days before or after the scheduled dosing day
- oral treatment can be used if a patient plans to miss a scheduled injection visit by more than 7 days. For oral therapy durations greater than two months, an alternative oral regimen is recommended.
- the injections must be administered by a healthcare professional, which will increase the number and duration of appointments within the service
- the service considers that cabotegravir/rilpivirine injections would be advantageous for patients with swallowing difficulties, poor oral absorption and may provide increased confidentiality for offshore workers
- patient numbers will be small with the potential to increase as the service gains experience
- cost offset will be available as patients would have previously been treated with another antiretroviral therapy
- since writing the papers for the meeting the team has become aware that national guidance is being developed for the introduction of cabotegravir and rilpivirine
- Greater Glasgow and Clyde Health Board and Tayside Health Board have recorded their formulary status as 'local implementation pending service planning and national guidance'
- without clear inclusion criteria, protocols etc., there is a risk of inequity of access for patients
- patient selection is important as patients must be able to attend the clinic for injections
- concerns were raised over the potential for drug interactions if treatment is not disclosed to the onshore or offshore medical staff
- it may not be possible to maintain confidentiality as off-shore employees may need to take a supply of oral tablets with them just in case they are delayed offshore and unable to make their scheduled appointment
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of cabotegravir and rilpivirine injections

The Group accepted that there is a restricted local need for the cabotegravir/rilpivirine long-acting antiretroviral therapy regimen, but agreed that implementation plans including national guidance are required to allow introduction.

SMC 2376 - Cabotegravir 30mg film-coated tablets, 600mg prolonged-release suspension for injection (Vocabria®) ▼ is not routinely available as local implementation plans are being developed.
Indication under review: in combination with rilpivirine prolonged-release injection, for the treatment of Human Immunodeficiency Virus type1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class.
Cabotegravir 600mg prolonged release injection plus rilpivirine 900mg prolonged-release injection every 2-months was non-inferior to cabotegravir 400mg plus rilpivirine 600mg every month in terms of the proportion of patients losing virological suppression in a phase III study. Cabotegravir 400mg prolonged release injection plus rilpivirine 600mg prolonged-release injection was non-inferior to oral antiretroviral therapy.
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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	SMC 2376 - Rilpivirine 25mg film-coated tablets (Edurant®), 900mg prolonged-release suspension for injection (Rekambys®) ▼ is not routinely available as local implementation plans are being developed. **Indication under review: in combination with cabotegravir prolonged-release injection, for the treatment of Human Immunodeficiency Virus type1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class.** **Cabotegravir 600mg prolonged release injection plus rilpivirine 900mg prolonged-release injection every 2-months was non-inferior to cabotegravir 400mg plus rilpivirine 600mg every month in terms of the proportion of patients losing virological suppression in a phase III study. Cabotegravir 400mg prolonged release injection plus rilpivirine 600mg prolonged-release injection was non-inferior to oral antiretroviral therapy.** **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**

8.5. FG1SMC 2284 - PERTUZUMAB (BREAST CANCER) AND

FG1SMC 2364 - PHESGO® ▼ (BREAST CANCER)

There were no declarations of interest recorded in relation to these products.

The Group considered the requests for pertuzumab intravenous infusion (SMC 2284) and Phesgo® ▼ subcutaneous injection (SMC 2364).

The Group noted:

- Phesgo® ▼
  - is a subcutaneous injection containing a fixed-dose combination of pertuzumab and trastuzumab
  - injection is administered over 8 minutes for the first injection and 5 minutes for subsequent injections, with an observation period of 30 minutes for the first injection and 15 minutes for subsequent injections
  - has the advantage of reduced administration/observation time compared to the intravenous (IV) preparations, aseptic preparation is not required, is more convenient for patients
- the safety and efficacy of Phesgo® ▼ is comparable to IV pertuzumab/trastuzumab
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of Phesgo® ▼
- pertuzumab IV:
  - is currently included on formulary in line with the SMC advice for neoadjuvant early breast cancer (EBC) (SMC 2120) and metastatic breast cancer (MBC) (SMC 2119)
  - is administered every three weeks as a 30 to 60 minute IV infusion followed by a 30 to 60 minute observation period
  - is not currently included on formulary for use [in combination with trastuzumab and chemotherapy] in the adjuvant treatment of adults with HER2-positive EBC at high risk of recurrence in patients with lymph node-positive disease
- in the adjuvant setting, pertuzumab IV is given for up to 18 cycles (~1 year)
- Phesgo® ▼ will be the preferred choice for patients requiring treatment however the service has asked that pertuzumab IV remains on formulary for the SMC approved indications
- SMC 2284 takes account of the benefits of a PAS that improves the cost-effectiveness of pertuzumab IV, and the SMC advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting

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The Group accepted the restricted local need for Phesgo® ▼ for the treatment of EBC and MBC as outlined in SMC 2364.

SMC 2364 - Phesgo® 1,200mg/600mg, 600mg/600mg solution for injection (pertuzumab/trastuzumab) ▼ is routinely available in line with national guidance (SMC 2364).
Indication under review:
Early breast cancer (EBC)
In combination with chemotherapy in:
- **the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence**
- **the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence**

Metastatic breast cancer (MBC)
- **in combination with docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.**

Restriction: restricted to use in line with previous SMC advice for pertuzumab and trastuzumab (SMC 2284; SMC 2120; SMC 2119; SMC No. 928/13; SMC No. 278/06).
Pertuzumab/trastuzumab (Phesgo®) ▼ provides a combination injection for subcutaneous use.
Pertuzumab has previously been accepted by SMC under the orphan medicine process.
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. Phesgo® should only be initiated under the supervision of a physician experienced in the administration of anti-cancer agents. Phesgo® should be administered by a healthcare professional prepared to manage anaphylaxis and in an environment where full resuscitation facilities are immediately available. In order to prevent medication errors, it is important to check the vial label to ensure that the medicinal product being prepared and administered is Phesgo®. FTEAM

The Group accepted the restricted local need for pertuzumab infusion for use in combination with trastuzumab and chemotherapy in the adjuvant treatment of adults with HER2-positive EBC, lymph node-positive disease and at high risk of recurrence, as outlined in SMC 2284.

SMC 2284 Pertuzumab 420mg concentrate solution for infusion (Perjeta®) is routinely available in line with national guidance (SMC 2284).
Indication under review: for use in combination with trastuzumab and chemotherapy in the adjuvant treatment of adults with HER2-positive early breast cancer at high risk of recurrence.
Restriction: for use in adults with lymph node-positive disease.
The addition of pertuzumab to trastuzumab and chemotherapy improved invasive disease-free survival in patients with HER2-positive early breast cancer at high risk of recurrence.
This advice applies only in the context of approved NHS Scotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/list prices that are 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. Pertuzumab should only be initiated under the supervision of a physician experienced in the administration of anti-

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cancer agents. Pertuzumab should be administered by a healthcare professional prepared to manage anaphylaxis and in an environment where full resuscitation facilities are immediately available. **FTEAM**

8.6. SMC 2392 – MIDAZOLAM (SEDATION (PAEDIATRICS))

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

Ms Hay confirmed that the Paediatric Service does not wish to include midazolam, as the brand Ozalin®, on the formulary.

Ms Hay confirmed that the Paediatric Service has some safety concerns related to the potential introduction of this oral midazolam product:

- it is presented in a glass ampoule and is the same concentration as the intravenous midazolam preparation, so there is a risk of confusion and inappropriate administration of the preparations
- administration is via a graduated oral applicator, and the applicator is graduated by bodyweight rather than milligrams or millilitres
- Ozalin® has a different concentration/dose to the current oral midazolam preparations used (250micrograms/kg vs.500micrograms/kg)

The Group accepted the Paediatric Service's position that midazolam, as the brand Ozalin®, would not be added to the formulary as there is a preference for alternative medicines.

SMC 2392 - Midazolam 2mg/mL oral solution in single-dose container (Ozalin®) is not routinely available as there is a local preference for alternative medicines.
Indication under review: in children from 6 months to 17 years old, for moderate sedation before a therapeutic or diagnostic procedure or as premedication before anaesthesia.
Ozalin® 2mg/mL oral solution is supplied in single-use glass ampoules and the dose must be measured using the oral applicator, which is graduated in kg of body weight, and the filter straw provided.
The availability of midazolam oral solution (Ozalin®) provides a licensed alternative to an unlicensed preparation.
Not routinely available as there is a local preference for alternative medicines. **FTEAM**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED DECEMBER 2021

The Group noted the SMC provisional advice issued December 2021.

If the negative SMC recommendation and non-submission statement are published next month, these medicines will not be included on the formulary for the indications in question.

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS – PUBLISHED DECEMBER 2021

The Group noted the SMC advice published December 2021.

Following publication of the negative SMC recommendation for tafamidis (Vyndaqel®)▼ SMC 2426 and the non-submission statements, for anakinra (Kineret®) SMC 2449 and nitisinone (Orfadin®) SMC 2450, 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 2368 olaparib (Lynparza®)

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- SMC 2387 ibrutinib (Imbruvica®) (submission received)
- SMC 2394 nivolumab (Opdivo®)
- SMC 2395 tirbanibulin (Klisyri®) ▼ (submission received)
- SMC 2372 buprenorphine implant (Sixmo®) ▼
- SMC 2432 amikacin liposomal nebuliser dispersion (Arikayce®)

Local advice for these medicines and indications will be included in the December 2021 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

SMC 2418 - RYALTRIS® (OLOPATADINE HYDROCHLORIDE/MOMETASONE FUROATE MONOHYDRATE) (ALLERGIC RHINITIS)

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

The Group discussed the SMC advice for Ryaltris® [in adults and adolescents 12 years of age and older] for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis (SMC 2418).

Ms Doney confirmed that:

- the service does not wish to include Ryaltris® on the formulary at this time because:
  - there are no comparative efficacy data against the relevant comparator Dymista® (fluticasone with azelastine nasal spray). There is no evidence that it is more effective.
  - Dymista® has a longer in-use shelf life of six months, whereas Ryaltris® expires two months after opening. Which may be a relevant consideration for people that use these treatments on an 'as-required' basis.
- costs are comparable, Ryaltris® costs marginally less than Dymista®

The Group agreed that Ryaltris® would not be included on the formulary for allergic rhinitis as there is a preference for alternative medicines.

SMC 2418 - Ryaltris® 600micrograms/25micrograms per actuation (olopatadine hydrochloride/mometasone furoate monohydrate) nasal spray is not routinely available as there is a local preference for alternative medicines.
Indication under review: in adults and adolescents 12 years of age and older for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis.
Restriction: for use where monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.
Olopatadine hydrochloride / mometasone furoate monohydrate (Ryaltris®) offers an additional treatment choice of antihistamine and glucocorticoid in a single nasal spray. SMC has previously accepted an alternative antihistamine / glucocorticoid combination for use in allergic rhinitis.
For patients in whom the combination of olopatadine hydrochloride plus mometasone furoate monohydrate is an appropriate choice of therapy, Ryaltris® provides the two ingredients in a single nasal spray.
Not routinely available as there is a local preference for alternative medicines. **FTEAM**

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM

Nil of note.

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12. DOCUMENTS FOR INFORMATION

The items 12.1, 12.2 (Drug Safety Update November and December 2021), item 12.3 (Antimicrobial Management Team minute August 2021), item 12.4 (Medicine Guidelines and Policies Group minute June 2021), item 12.5 (Grampian Area Drug and Therapeutics Committee (GADTC) minute June 2021), and item 12.6 (Bugs and Drugs Volume 3) were noted.

Ms Davie highlighted that DSU November 2021 'Adrenaline auto-injectors: reminder for prescribers to support safe and effective use' could be linked with the adrenaline update provided by Dr Herriot. **FTEAM**

13. AOCB

ULIPRISTAL ACETATE 5MG TABLETS (ESMYA®)

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

Ms Doney provided the Group with an update on the status of the licensing and marketing of ulipristal 5mg tablets (Esmya®).

Ms Doney confirmed that:
- Esmya® was previously included on the formulary, however the licence was suspended in March 2020
- June 2021 Esmya® was marketed again in the UK but with a much narrower licence
- the service does not wish to add it to formulary for its revised indication, if a local need is identified specialists will request it for individual patients, and restrict use to the managed service
- the ScriptSwitch profile will be checked to note it as non-formulary, and ensure no prescribing on repeat prescriptions **KN**

The Group agreed that ulipristal 5mg tablets would not be included on the formulary for the intermittent treatment of uterine fibroids.

Ulipristal acetate 5mg tablets (Esmya®) is not routinely available in NHS Grampian. Indication under review: for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women who have not reached menopause when uterine fibroid embolisation and/or surgical treatment options are not suitable or have failed. Not routinely available in NHS Grampian. **FTEAM**

RESPIRATORY MCN PRESCRIBING GUIDANCE FOR ASTHMA AND COPD (ADULTS)

Ms Doney confirmed that:
- the respiratory Managed Clinical Network has updated its prescribing advice for the management of asthma and COPD in adults
- the advice is published on Grampian Guidance and the formulary
- the formulary entries will be updated to reflect the changes **FTEAM**

DATE OF NEXT MEETING

Tuesday 18 January 2022 starting at 14.30 via Microsoft Teams.

CHAIRMAN'S SIGNATURE _____ **DATE 18 JANUARY 2022**