NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 20 April 2021 at 14:30 via Microsoft Teams

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

IN ATTENDANCE
Ms Christine Hay, Formulary and Medicines Management Pharmacist
Mrs Sarah O'Beirne, Lead Pharmacist, Grampian Medicines Information Centre (observer)
Mrs Aimee Smith, Rotational Pharmacist (observer)

ITEM	SUBJECT	ACTION
	The Chairman welcomed members, opened the meeting and noted that a quorum was present.	
1.	**APOLOGIES**	
	Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 16 MARCH 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 in the agenda.	**FTEAM**
5.	**FORMULARY GROUP DECISIONS MARCH 2021 – PUBLISHED – 29/03/2021**	
	Members ratified the decisions of the March 2021 meeting as published.	**FTEAM**
6.	**NETFORMULARY/FORMULARY REVIEW**	
6.1.	**93-DAY REPORT**	
	The Chairman highlighted the content of the Formulary Team's '93-day deadline report for Formulary Group decisions'. For the time-period April 2020 to March 2021 the Formulary Group audit standard (90%) for 93-day deadline reporting was achieved - 100% of entries updated within 93 days.	
6.2.	**PAEDIATRIC LICENCE EXTENSIONS (HIV)**	
	Dr Fitton declared a personal, non-specific interest in Gilead and took part in decision-making. The Group considered the Formulary Team's proposed recommendations for some paediatric licence extensions for medicines indicated for the treatment of Human	

ITEM	SUBJECT	ACTION

Immunodeficiency Virus (HIV-1).

The Group noted that, when used in children and adolescent patients:
- prescribing will only be on the advice of specialists in paediatric HIV, with advice from specialists in other Health Boards where appropriate
- costs will be subject to the current pricing arrangements
- patient numbers will be very small or none, but local approval will bring use in line with the adult service and/or prevent delay in access should a local need be identified

Ms Doney confirmed that the classification 'recommended for hospital use only' does not prevent supply of medicines by Primary Care, e.g. use of hospital-based prescription (HBP) stationery.

ETRAVIRINE 25MG, 100MG, 200MG TABLETS (INTELENCE®)

Ms Doney confirmed that etravirine 25mg, 100mg, 200mg tablets (Intelence®) is already included on the formulary for HIV-1 infected adults, adolescents and children 6 years and older. The licence extension lowers the age to include children aged from 2 years to less than 6 years.

The Group supported extending the formulary inclusion to include children from 2 to less than 6 years, in line with current licensing.

Etravirine 25mg, 100mg, 200mg tablets (Intelence®) is routinely available in line with local guidance.
Indication under review: in combination with a boosted protease inhibitor and other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced adult patients and in antiretroviral treatment-experienced paediatric patients from 2 years to <6 years of age.
Restriction: to be prescribed under the supervision of specialists in paediatric HIV.
It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. **FTEAM**

EMTRICITABINE/TENOFOVIR 200MG/245MG FILM-COATED TABLETS

Ms Doney confirmed that:
- the fixed-dose combination of emtricitabine 200mg plus tenofovir disoproxil 245mg film-coated tablets, is already included on the formulary for the treatment of HIV-1 in adults
- generic combination preparations are now available and the combination is licensed:
  1) in antiretroviral combination therapy for the treatment of HIV-1 infected adults
  2) for the treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents

The Group supported extending the formulary inclusion to include use in adolescents (12 years to less than 18 years) in line with current licensing.

Emtricitabine/tenofovir 200mg/245mg film-coated tablets is routinely available in line with local guidance.
Indication under review: for the treatment of HIV-1 infection in adolescents (12 years to <18 years, weighing at least 35kg), with NRTI resistance or toxicities precluding the use of first-line agents
Restriction: to be prescribed under the supervision of specialists in paediatric HIV.
It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. **FTEAM**

ITEM	SUBJECT	ACTION

COBICISTAT 150MG TABLET (TYBOST®)

Ms Doney confirmed that:

- the licence of single-agent cobicistat for the treatment of HIV-1 has been extended to include adolescents aged 12 years to less than 18 years, weighing at least 35kg when co-administered with atazanavir, or weighing at least 40kg when co-administered with darunavir
- cobicistat has no antiviral activity, but when used in combination antiviral agents like atazanavir or darunavir it enhances their systemic exposure
- cobicistat, as a single-agent product, is not currently included on the formulary
- the cobicistat licence extension also affects single-agent darunavir or atazanavir and combination antiretroviral tablets containing cobicistat with darunavir or atazanavir
  - single-agent darunavir, as several strengths and formulations, is included on the formulary. Although available as generic preparations, only the reference product Prezista® includes the paediatric licence extension to include dosing with cobicistat.
  - Rezolsta®, a fixed-dose combination tablet containing darunavir 800mg and cobicistat 150mg, is included on the formulary in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in adults. It is now licensed in adults and adolescents (aged 12 years and older, weighing at least 40kg).
  - Stribild®, a fixed-dose quadruple component tablet containing elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg and tenofovir disoproxil 245mg, is included on the formulary for the treatment of HIV-1 infection in adults. It is now licensed for adolescents (12 years to less than 18 years, weighing at least 35kg).

The Group supported:

- extending the 'non-formulary' status of single-agent cobicistat, including use in combination with single-agent darunavir (Prezista®), to include adolescents from 12 years to less than 18 years
- reviewing the formulary position of single-agent darunavir, when/if generic preparations gain the paediatric licence extension co-administered with cobicistat
- extending the formulary acceptance for the fixed-dose combinations Rezolsta® and Stribild® to include adolescents from 12 years to less than 18 years

Cobicistat 150mg tablet (Tybost®) is not routinely available in NHS Grampian.
Indication under review: as a pharmacokinetic enhancer of atazanavir 300mg once daily or darunavir 800mg once daily as part of antiretroviral combination therapy in human immunodeficiency virus-1 (HIV-1) infected adolescents aged 12 years to < 18 years:

- **weighing at least 35kg co-administered with atazanavir or**
- **weighing at least 40kg co-administered with darunavir.**

Not recommended for use in NHS Grampian. **FTEAM**

Darunavir 400mg, 800mg film-coated tablets, 100mg/mL oral suspension (Prezista®) is not routinely available in NHS Grampian.
Indication under review: co-administered with cobicistat is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adolescents aged 12 years to <18 years.
Not recommended for use in NHS Grampian. **FTEAM**

Rezolsta® 800mg/150mg film-coated tablets (darunavir/cobicistat) is routinely available in line with local guidance.
Indication under review: in combination with other antiretroviral medicinal products, for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and adolescents (aged 12 years and older, weighing at least 40kg).

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	Genotypic testing should guide its use. **Restriction: to be prescribed under the supervision of specialists in HIV/paediatric HIV.** **It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.**	**FTEAM**
	Stribild® 150mg/150mg/200mg/245mg film-coated tablet (elvitegravir/cobicistat/ emtricitabine/tenofovir disoproxil (as fumarate)) is routinely available in line with local guidance. **Indication under review: for the treatment of HIV-1 infection in adolescents aged 12 to <18 years weighing at least 35kg who are infected with HIV-1 without known mutations associated with resistance to any of the three antiretroviral agents in Stribild® and who have experienced toxicities which preclude the use of other regimens that do not contain tenofovir disoproxil** **Restriction: to be prescribed under the supervision of specialists in paediatric HIV.** **It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.**	**FTEAM**

7. OTHER BUSINESS

7.1. DISCONTINUATION OF FLUTIFORM K-HALER®

Napp, the Marketing Authorisation Holder (MAH) of Flutiform K-haler® confirmed that the K-haler® device will be withdrawn from the market (125microgram/5microgram strength in April 2021 and 50microgram/5microgram strength in August 2021).
Withdrawal is due to commercial reasons, the complex and costly manufacture of the product means it is no longer commercially viable.

The K-haler® device is breath-triggered pMDI that was included on the formulary in January 2019. Flutiform® pMDI 50microgram/5microgram, 125microgram/5microgram (and a higher strength 250microgram/10microgram) pressurised metered-dose inhaler (pMDI) will remain available and are included in the local prescribing guidance.

Ms Doney confirmed that the Grampian Respiratory MCN is aware of the discontinuation and the local prescribing guidance is being reviewed to remove Flutiform K-haler®, and that colleagues in the Medicines Management Team are liaising with the MCN and Primary Care to highlight the need for change of prescription for relevant patients.

The Group noted the discontinuation of Flutiform K-haler®.

SMC 2016 - Flutiform K-haler® 50microgram/5microgram, 125microgram/5microgram pressurised inhalation, suspension (fluticasone propionate/ formoterol fumarate) is now withdrawn from use/discontinued.
Indication: for the regular treatment of asthma where the use of a combination product [an inhaled corticosteroid (ICS) and a long-acting beta2-agonist (LABA)] is appropriate:
- for patients not adequately controlled with ICS as 'as required' inhaled short-acting beta2-agonist or
- for patients already adequately controlled on both ICS and a LABA
This medicine is now withdrawn from use/discontinued. **FTEAM**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2300 - FOSTAMATINIB (CHRONIC IMMUNE THROMBOCYTOPENIA (ITP))

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

The Group considered the request for fostamatinib for the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments.

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The Group noted:

- the MAH requested that SMC considered fostamatinib for the treatment of patients with severe symptomatic ITP or with a high risk of bleeding who have not had a suitable response to other therapies, including a thrombopoietin receptor-agonist (TPO-RA), or where use of a TPO-RA is not appropriate
- fostamatinib was accepted by SMC for restricted use in NHS Scotland following a full submission considered under the orphan equivalent process. Acceptance was subject to the output from the Patient and Clinician Engagement (PACE) process.
- the recommended starting dose is 100mg twice daily. The dose can be increased to 150mg twice daily after four weeks based on platelet count and tolerability.
- dosing requirements must be individualised based on the patient's platelet counts
- treatment should be discontinued after 12 weeks if the platelet count does not increase to a level sufficient to avoid clinically important bleeding
- efficacy is relatively low, with the expectation that ~ 20% of patients will respond to treatment
- the SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of fostamatinib, and the PAS is not available in Primary Care
- fostamatinib represents a new cost to the service with minimal offset available from displacement of other agents

The Group accepted the restricted local need for fostamatinib for the treatment of chronic ITP as outlined in SMC 2300. Additionally, the Group requested that a message is actioned on the ScriptSwitch profile to highlight that fostamatinib should not be prescribed in Primary Care. **KN**

SMC 2300 - Fostamatinib 100mg, 150mg film-coated tablets (Tavlesse®)▼ is routinely available in line with national guidance (SMC 2300).
Indication under review: treatment of chronic immune thrombocytopenia (ITP) in adult patients with severe symptomatic ITP or with a high risk of bleeding who are refractory to other treatments, including a thrombopoietin receptor-agonist (TPO-RA), or where use of a TPO-RA is not appropriate.
Fostamatinib has been shown to be significantly 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 is equivalent or lower.
This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. Fostamatinib treatment should be initiated and remain under the supervision of a physician who is experienced in the treatment of haematological diseases. **FTEAM**

8.2. FG1SMC 2137 - CARIPRAZINE (SCHIZOPHRENIA IN ADULTS)

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

The Group considered the request for cariprazine for the treatment of schizophrenia in adults.

The Group noted:

- cariprazine:
  - was accepted for restricted use in NHS Scotland following a full submission reviewed by SMC
  - [like some other antipsychotic agents] causes significant weight gain, and patients

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should have their weight monitored regularly
  - should be used with caution in patients with risk factors for stroke, known cardiovascular disease or a family history of QT prolongation/patients treated with drugs that might cause QT prolongation
- the MAH requested that the SMC considered cariprazine when positioned for use as second-line therapy in patients with schizophrenia, where predominant negative symptoms (PNS) have been identified as an important feature
- the service is requesting prescribing in Primary Care on the recommendation of a specialist
- cost offset is available from the displacement of other antipsychotic agents
- the Summary of Product Characteristics (SmPC) states that '*Women of child bearing potential must use highly effective contraception while taking cariprazine and for at least 10 weeks after stopping treatment. Women using systemically acting hormonal contraceptives should add a second barrier method''*
- if accepted, the Principal Pharmacist for Mental Health and Learning Disability Services has requested that the contraceptive advice is highlighted on the formulary entry for cariprazine

Members noted that cariprazine, like some other anti-schizophrenic drugs, should be used cautiously in patients with known cardiovascular disease or in patients with a family history of QT prolongation and in patients treated with medicinal products that might cause QT prolongation.

Mrs Neave will check prescribing systems to see if an interaction warning occurs when co-prescribing cariprazine with medicines that can extend the QT interval. **KN**

Dr Metcalfe confirmed that:
- the ECG (electrocardiogram) department already has a protocol set up for careful QTc monitoring
- prescribers should be reminded that if starting an antipsychotic drug that they should consider doing an ECG to measure QTc before initiation
- GPs should be reminded of the availability of the high-quality rapid-return reporting process for ECGs

Members considered that as the decision to prescribe is the Consultants decision, it should be Mental Health that checks if the patient is suitable for treatment, and the initial assessment may include an ECG.
As GPs' continue treatment, then it is the responsibility of the prescriber to continue to monitor as part of the annual mental health review. The need to monitor ECG should be flagged to Primary Care at handover.

The Group accepted the restricted local need for cariprazine for the treatment of adults with schizophrenia after treatment of at least one prior therapy, as outlined in SMC 2137.

SMC 2137 - Cariprazine 1.5mg, 3mg, 4.5mg, 6mg hard capsules (Reagila®)▼ is routinely available in line with local guidance.
Indication under review: for use second-line onwards, for the treatment of schizophrenia in adults where predominantly negative symptoms have been identified as an important feature.
In patients with stable schizophrenia with predominantly negative symptoms, cariprazine improved negative symptoms more than another second-generation antipsychotic.
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**

8.3. FG1SMC 2279 - ATEZOLIZUMAB (EXTENSIVE STAGE SMALL CELL LUNG CANCER)

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

The Group considered the request for atezolizumab in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

The Group noted:

- atezolizumab:
  - [for this indication] is used in combination with carboplatin and etoposide. Addition of atezolizumab to current duplet chemotherapy provided improved overall survival (OS) and progression-free survival (PFS) [at median follow up of 13.9 months; OS 12.3 versus 10.3 months; PFS 5.2 versus 4.3 months].
  - [for this indication] was accepted for use within NHS Scotland, following a full submission assessed under the end of life and orphan medicine process. The SMC advice takes account of the views from a PACE meeting.
  - is administered by intravenous infusion every three weeks
  - is administered with carboplatin and etoposide for the first four cycles, before continuation as monotherapy
  - represents a new cost to the service
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of atezolizumab
- in the trial, patients received a median of seven cycles, however this ranged from 1 to 30 cycles
- patient numbers are small, and duration of treatment is variable. The wide range of durations of treatment makes estimating the financial implications problematic.
- introduction of atezolizumab will have service implications for the clinic (staff, consumables, chair-time etc.) and the Aseptic Unit (preparation of triplet therapy instead of duplet therapy, and ongoing atezolizumab maintenance therapy)
- patients with contraindications to immunotherapy or who are unsuitable for immunotherapy in combination with chemotherapy will continue to receive carboplatin-etoposide

The Group accepted the restricted local need for atezolizumab in combination with carboplatin and etoposide for the first-line treatment of adult patients with ES-SCLC, as outlined in SMC 2279.

SMC 2279 - Atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq®)▼ is routinely available in line with national guidance (SMC 2279).
Indication under review: in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
In one randomised, double-blind phase III study, the combination of atezolizumab with carboplatin and etoposide was associated with modest significant improvements in progression free survival and overall survival compared with chemotherapy alone in adult patients with untreated ES-SCLC.
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 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. Atezolizumab must be initiated and supervised by physicians experienced in the treatment of cancer. **FTEAM**

8.4. FG1 434/20 - MOXIFLOXACIN ((OFF-LABEL) ENDOPHTHALMITIS)

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

The Group considered the request for off-label use of moxifloxacin for the treatment of bacterial endophthalmitis in adults.

The Group noted:

- use for this indication will be off-label
- moxifloxacin, at a dose of 400mg daily for 10 days, is included in Moorfields Eye Hospital Antimicrobial Adult Guide for the management of bacterial endophthalmitis
- the service plans to treat with 400mg daily for 5 to 10 days
- the evidence available is of low quality, but it was included in an occasional update from The Royal College of Ophthalmologists - *Recent advance in Endophthalmitis Management (Summer 2014)*
- a study suggested clinical superiority of oral moxifloxacin 400mg daily for 10 days over ciprofloxacin, with quicker resolution of hypopyon, reduced need for repeat intravitreal injection and better chance of a good clinical outcome
- the service plan to supply moxifloxacin from the managed service
- patient numbers and costs are relatively small, and there is a small cost offset available as moxifloxacin will displace the use of ciprofloxacin
- the service has put together a detailed endophthalmitis protocol which is based on the Moorfield Endophthalmitis Guidelines
- the Antimicrobial Management Team (AMT) are aware of and support this submission from ophthalmology for oral moxifloxacin 400mg daily for 10 days
- the service plans to provide all patients receiving moxifloxacin for endophthalmitis with the MHRA patient information leaflet - *Fluoroquinolone antibiotics (-oxacins): what you need to know about side effects of tendons, muscles, joints, and nerves*

Members noted the different treatment duration between the local and Moorfield protocols. The difference will be raised with the service. **FTEAM**

The Group accepted the restricted local need for the off-label use of moxifloxacin for the treatment of bacterial endophthalmitis in adults.

Moxifloxacin 400mg film-coated tablets is routinely available in line with local guidance.
Indication under review: [off-label use] for the treatment of bacterial endophthalmitis in adults.
It was classified 3b - licensed product available for restricted off-label use and 8b - recommended for hospital use only.
Consideration should be given to official guidance on the appropriate use of antibacterial agents. **FTEAM**

8.5. FG1SMC 2297 - DAROLUTAMIDE (NON-METASTATIC CASTRATION RESISTANT PROSTATE CANCER)

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

The Group considered the request for darolutamide for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.

The Group noted:

- darolutamide:
  - is taken orally as 600mg (two tablets of 300mg) twice daily, equivalent to a total daily dose of 1200mg. Luteinising hormone-releasing hormone analogue should be continued during treatment of patients not surgically castrated.
  - [for this indication] meets SMC orphan equivalent criteria and was accepted for use

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within NHS Scotland following a full submission reviewed by the SMC executive
- currently there are no standard treatments for this patient group
- the 2020 update of the ARAMIS study showed that during the combined double-blind and open-label periods the median duration of exposure increased to 25.8 months
- patient numbers are small, but darolutamide represents a new cost to the service
- cost will be cumulative as patients may be taking darolutamide for over 2 years
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of darolutamide, and the PAS is not available in Primary Care
- although no direct cost offset is available, for patients progressing on darolutamide with metastatic disease, there is a low likelihood of these patients being treated with either abiraterone or enzalutamide for castrate-resistant metastatic prostate cancer. The mechanisms for resistance to darolutamide appear to be the same as for abiraterone and enzalutamide, making it highly likely that these are all cross-resistant.

The Group accepted the restricted local need for darolutamide for the treatment of men with nmCRPC who are at high risk of developing metastatic disease.

SMC 2297 - Darolutamide 300mg film-coated tablets (Nubeqa®)▼ is routinely available in line with national guidance (SMC 2297)
Indication under review: for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.
In a phase III study in men with high risk nmCRPC, treatment with darolutamide was superior to placebo for metastasis-free survival. High risk was defined as prostate specific antigen (PSA) doubling time ≤10 months and PSA ≥2 nanograms/mL. Both groups received on-going androgen-deprivation therapy or had undergone bilateral orchiectomy.
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 a specialist physician experienced in treatment of prostate cancer. **FTEAM**

Items 8.6 and 8.7 were taken together.

8.6. FG1SMC 2332 - DORAVIRINE (HIV-1 (ADULTS)) AND

8.7. FG1SMC 2333 - DELSTRIGO® (DORAVIRINE/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE) (HIV-1 (ADULTS))

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

The Group considered the two requests for doravirine as licensed for the treatment of adults infected with HIV-1.

The Group noted:
- doravirine:
  - is a non-nucleoside reverse transcriptase inhibitor (NNRTI), licensed for the treatment of adults infected with HIV-1
  - as the single-agent product Pifeltro®▼, and the fixed-dose combination product Delstrigo®▼, was accepted for use in NHS Scotland following abbreviated submissions reviewed by the SMC Executive
  - has fewer drug interactions, in particular none with acid-reducing agents, and can be taken with or without food
  - has a more favourable lipid profile, lower incidence of rash, and fewer central nervous system side effects than efavirenz

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- will become a preferred choice NNRTI, and Delstrigo®▼ will become the first-line NNRTI-based single-tablet regimen

The Group accepted the restricted local need for doravirine, as a single agent Pifeltro®▼ and fixed-dose combination Delstrigo®▼, as licensed for the treatment of adults infected with HIV-1.

SMC 2332 - Doravirine 100mg film-coated tablets (Pifeltro®)▼ is routinely available in line with national guidance (SMC 2332)
Indication under review: in combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class.
Doravirine offers an additional treatment choice in the therapeutic class of NNRTIs for this indication.
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 should be initiated by a physician experienced in the management of HIV infection. **FTEAM**

SMC 2333 - Delstrigo® 100mg/300mg/245mg film-coated tablets (doravirine/lamivudine/tenofovir disoproxil)▼ is routinely available in line with national guidance (SMC 2333).
Indication under review: for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, lamivudine, or tenofovir.
Doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo®) offers an additional treatment choice of NNRTI-based single-tablet regimen for this indication.
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 should be initiated by a physician experienced in the management of HIV infection. **FTEAM**

Note: The classification 'hospital use only' does not prevent supply of medicines by Primary Care, e.g. use of HBP stationery.

8.8. FG1SMC 2335 - TRIMBOW® (ADULT ASTHMA)

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

The Group considered the SBAR submitted on behalf of the Respiratory Managed Clinical Network (MCN).

The Group noted:
- asthma is a chronic disease with poor outcomes if not managed well
- asthma exacerbations are associated with increased healthcare costs, and severe exacerbations are potentially life-threatening
- Trimbow® [87/5/9]:
  - is a combination pressurised metered dose inhaler (pMDI) that contains a medium dose of inhaled corticosteroid (ICS - beclometasone), plus a long-acting beta$_2$ agonist (LABA - formoterol) and long-acting muscarinic antagonist (LAMA - glycopyrronium)

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- is already included on the formulary for the management of chronic obstructive pulmonary disease, so is a known fixed-dose combination product and device
- in asthma, offers an additional treatment choice for patients and prescribers
- may be less confusing for patients as their medium dose ICS, LABA and LAMA are provided by a single device. Use of a single device may improve treatment adherence and positively affect a patient's asthma control.

The Group accepted the restricted local need for this fixed-dose inhaler, as licensed, for the maintenance treatment of asthma in adults. Use is subject to inclusion in the Respiratory MCN framework for inhaled medicines.

SMC 2235 - Trimbow® 87micrograms/5micrograms/9micrograms metered dose inhaler (beclometasone dipropionate/formoterol fumarate dihydrate/glycopyrronium) is routinely available in line with local guidance. Indication under review: maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and medium dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year.
It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care. Use is subject to inclusion in the Respiratory MCN framework for inhaled medicines. **FTEAM**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – APRIL 2021

The Group noted the SMC provisional advice issued April 2021.

If the non-submission statement is published next month, the medicine will not be included on the formulary for the indication in question.

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS – APRIL 2021

The Group noted the SMC advice published April 2021.

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

- SMC 2303 isatuximab (Sarclisa®) ▼ (submission expected)
- SMC 2317 dupilumab (Dupixent®) (submission received)
- SMC 2313 galcanezumab (Emgality®) ▼ (submission expected)
- SMC 2322 dapagliflozin (Forxiga®) (submission received)
- SMC 2346 and SMC 2348 acalabrutinib (Calquence®) ▼ (submissions received)

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

SMC 2327 – ATALUREN (DUCHENNE MUSCULAR DYSTROPHY RESULTING FROM A NONSENSE MUTATION)

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

The Group discussed the SBAR submitted regarding the use of ataluren for the treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 2 years and older.

The Group noted that:

- ataluren is a very expensive medicine licensed for a very rare disease. In 2016, it was not recommended for use within NHS Scotland (SMC 1131/16).
- subsequently, it has been validated as meeting the new SMC ultra-orphan criteria and

ITEM	SUBJECT	ACTION

has undergone an initial assessment of the evidence using the ultra-orphan framework (SMC 2327). This means that ataluren 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'
- the SG notifies Health Boards when this medicine is available for prescribing within the ultra-orphan pathway. Meantime, any requests to access treatment are considered through local non-formulary processes.
- until notification from SG these medicines are recorded as '*Not routinely available in NHS Grampian however if local need is identified: Contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI)*'.
- when availability for prescribing within the ultra-orphan pathway is confirmed the Formulary Team updates the advice to '*Not routinely available in NHS Grampian however if local need is identified: Treatment is available through the National Services Scotland: Ultra-Orphan Medicines Risk Share Scheme/ or Inherited Metabolic Disorders Risk Share Scheme*'.

SMC 2327 - Ataluren 125mg, 250mg, 1,000mg granules for oral suspension (Translarna®) ▼ is not routinely available in NHS Grampian.
Indication under review: for the treatment of Duchenne muscular dystrophy resulting from a nonsense mutation in the dystrophin gene, in ambulatory patients aged 2 years and older.
The presence of a nonsense mutation in the dystrophin gene should be determined by genetic testing
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 – APRIL 2021

Nil of note.

12. DOCUMENTS FOR INFORMATION

The Group noted items 12.1 (Drug Safety Update March 2021), 12.2 (MedWatch newsletter March 2021) and 12.3 (Advice on Health Technologies Quarterly bulletin April 2021) were noted.

13. AOCB

The Chairman confirmed that Mrs O'Beirne is the new Lead Pharmacist for the Grampian Medicines Information Centre. She is observing today and will officially join the Formulary Group next month.

DATE OF NEXT MEETING

Tuesday 18 May 2021 starting at 14.30 via Microsoft Teams.

CHAIRMAN'S SIGNATURE **DATE 18 MAY 2021**