

**NHS GRAMPIAN**  
**Minute of Formulary Group Meeting**  
**Tuesday 20 February 2024 at 14:30 via Microsoft Teams**

**PRESENT**

Ms L Cameron  
Dr V Chieng  
Dr D Culligan  
Ms F Doney (Vice-Chair)  
Dr L Elliot (Chair)  
Mrs S Howlett  
Mrs G McKerron  
Dr M Metcalfe (Vice-Chair)  
Mrs E Milne  
Mrs S O'Beirne  
Mr M Paterson  
Dr K Simpson  
Mr R Sivewright  
Mrs B Tiesmann

**APOLOGIES**

Ms A Davie

**APPROVED**

**IN ATTENDANCE**

Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team  
Mrs Christine Standen, Formulary and Medicines Management Pharmacist

<b>ITEM</b>	<b>SUBJECT</b>	<b>ACTION</b>
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WELCOME

The Chair welcomed members, opened the meeting, and noted that a quorum was present.

The Chair welcomed two new members, Dr Karen Simpson as a new GP representative, and Mrs Birgit Teismann as a deputy for the City Primary Care Lead Pharmacist.

**1. APOLOGIES**

Apologies for absence were requested and noted.

**2. MINUTE AND DECISIONS**

**2.1. DRAFT MINUTE OF THE MEETING HELD 16 JANUARY 2024**

Members 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 final approval.

**FD**

**2.2. FORMULARY GROUP DECISIONS JANUARY 2024 - PUBLISHED 29/01/2024**

Members ratified the decisions of the January 2024 meeting as published.

**3. MATTERS ARISING**

**3.1. ACTION LOG**

The action log was noted.

No additional items were identified for discussion at the meeting.

ITEM	SUBJECT	ACTION
3.2.	TEZEPelumAB (FEEDBACK FROM THE SERVICE)	
	<p>Mr Paterson declared a personal, non-specific interest in AstraZeneca UK Limited and took part in decision-making.</p> <p>The submission for tezepelumab (SMC 2541) was discussed at the December 2023 meeting. Members raised concerns about the imbalance in serious cardiac events highlighted [with the use of tezepelumab] in the long-term extension study and requested clarification of a few points:</p> <ul style="list-style-type: none"> <li>• the Group was unsure if all severe asthma clinic staff would be prescribers and queried how the potential risk of cardiac adverse events with this new medicine would be highlighted to all staff?</li> <li>• what does the service plan to do to monitor patients on tezepelumab, is it different to the other biologic agents used?</li> <li>• to support recognition of a possible cardiac adverse drug reaction what information, and how will the information about the risk of cardiac adverse events be shared with patients/relatives/carers and also colleagues in Primary Care?</li> <li>• is the process for ADR reporting highlighted to non-prescribing staff and patients/relatives/carers?</li> </ul> <p>The Service emailed a detailed response confirming that:</p> <ul style="list-style-type: none"> <li>• there are three consultants affiliated to the severe asthma service; these physicians are responsible for the prescribing of biologic therapies for asthmatic patients when considered clinically appropriate</li> <li>• for the biologic therapies already being used in our service, patients are monitored in the clinic environment for 2 hours after each of the first 2 doses. Routine clinical observations are recorded during these visits. We would envisage doing the same after the administration of tezepelumab.</li> <li>• we are aware that the SMC and SPC* have highlighted concerns about the potential risk of adverse cardiac events with tezepelumab. We have discussed this matter with a member of the medical affairs team from the manufacturer, and they advised on the below which is a summary of the text from the DESTINATION Study manuscript:                     <p><i>"While the incidence of cardiac serious adverse events was higher in those receiving tezepelumab than those receiving placebo. The incidence of cardiac adverse events, independently adjudicated major adverse cardiovascular events, and cardiovascular deaths was similar in tezepelumab and placebo recipients. There is no known biological mechanism by which blocking TSLP with tezepelumab would lead to cardiac pathophysiology, and the very low expression of TSLP and TSLP receptor mRNA in cardiac tissue suggests that signalling via the TSLP receptor pathway in these tissues is unlikely. The incidence of cardiac serious adverse events in tezepelumab-treated participants in DESTINATION is similar to those estimated from publicly available data of other biologics for severe asthma. The incidence of cardiac serious adverse events in the placebo group in DESTINATION was substantially lower than the incidence in studies of other biologics for severe asthma. Neither investigators nor a masked independent adjudication committee attributed causality to tezepelumab for any cardiac serious adverse event</i></p> <p><i>This data has been thoroughly interrogated by independent data monitoring committee AND various regulators from across the globe including the EMA and MHRA – they have independently concluded that:</i></p> <p><i>No causal relationship between Tezepelumab and these events was established</i></p> <p><i>No patient population at risk has been identified"</i></p> </li> </ul> <p>In light of this information and congruous with other centres already prescribing the drug, we have no plans for agent specific cardiovascular risk assessment or additional cardiovascular monitoring. We would, however, undertake a detailed cardiovascular</p>	

\* SPC/SmPC - Summary of product characteristics

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	<p>history and examination in patients being considered for this therapy (as is routinely done for all patients in our service prior to initiation of any biologic therapy) which may help inform the decision as to which biologic agent a patient ultimately receives.</p> <ul style="list-style-type: none"><li>• medical and nursing staff in the severe asthma service are all familiar with the process of reporting adverse effects via the yellow card process. For all biologic therapies, staff take every opportunity at various junctures of the patient journey to educate patients, relatives and carers about clinically relevant side effects to be vigilant for and of the importance of reporting these. This information can be tailored for tezepelumab as required and would incorporate the SPC recommendation to counsel patients of signs or symptoms suggestive of a cardiac event (for example, chest pain, dyspnoea, malaise, feeling lightheaded or faint) and to seek immediate medical attention if such symptoms occur.</li></ul> <p>Members discussed the additional information provided and accepted the restricted local need for tezepelumab as outlined in SMC 2541.</p> <p><b>SMC 2541 - Tezepelumab 210mg solution for injection in pre-filled syringe (Tezspire®) is routinely available in line with national guidance (SMC 2541). Indication under review: as an add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment and have either:</b></p> <p><b>(i) experienced at least three exacerbations in the previous year and are not receiving maintenance treatment with oral corticosteroids, or</b></p> <p><b>(ii) have blood eosinophils <math>\geq 150</math> cells/microlitre and are receiving maintenance treatment with oral corticosteroids.</b></p> <p><b>Compared with placebo, the addition of tezepelumab to inhaled corticosteroids and at least one additional controller medicine, significantly reduced the annual asthma exacerbation rate in patients with inadequately controlled severe asthma. 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 severe asthma.</b></p>	<p>FTEAM</p>
	<p><b>3.3. UPDATE - NPSA: VALPROATE: ORGANISATIONS TO PREPARE FOR NEW REGULATORY MEASURES FOR OVERSIGHT OF PRESCRIBING TO NEW PATIENTS AND EXISTING FEMALE PATIENTS</b></p> <p>Ms Doney confirmed that a meeting was held on 23 January to ensure that NHS Grampian [Orkney and Shetland] has a plan in place to implement the new regulatory measures for sodium valproate, valproic acid and valproate semisodium (valproate). A further meeting is planned for March.</p> <p>An action and implementation plan has been produced with reporting to the Grampian Area Drugs and Therapeutics Committee (GADTC).</p> <p>Item closed.</p>	<p>FTEAM</p>
	<p><b>3.4. DECLARATION OF INTEREST FOR CALENDAR YEAR 2023</b></p> <p>The Chair reminded members to return their conflicts of interest for calendar year 2023.</p>	
	<p><b>3.5. UPDATE - NICE/SMC COLLABORATION ON MTA FOR SMALL MOLECULE CYSTIC FIBROSIS DRUGS</b></p> <p>It was confirmed that publication of the NICE/SMC collaboration multiple technology</p>	

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	appraisal for small molecule cystic fibrosis drugs has been delayed with the anticipated date of final guidance still to be confirmed.	
	<b>3.6. MEMBER SURVEY</b>	
	The Chair requested that members complete the survey as soon as possible.	<b>ALL</b>
<b>4.</b>	<b>PRESENTATIONS</b>	
	None.	
<b>5.</b>	<b>NEW PRODUCT REQUESTS</b>	
	<b>5.1. SMC 2605 - BIMEKIZUMAB (ACTIVE PSORIATIC ARTHRITIS) AND SMC 2616 - BIMEKIZUMAB (ACTIVE AXIAL SPONDYLOARTHRITIS)</b>	
	There were no declarations of interest recorded in relation to this product.	
	The Group considered the request for bimekizumab for the treatment of adults with active psoriatic arthritis (PsA), active non-radiographic axial spondyloarthritis (nr-axSpA) or active ankylosing spondylitis (AS) who have not responded adequately to conventional therapy.	
	The Group noted that:	
	<ul style="list-style-type: none"><li>the two SMC advice documents take account of the benefits of a PAS that improves the cost-effectiveness of bimekizumab</li><li>bimekizumab:<ul style="list-style-type: none"><li>is a monoclonal antibody designed to attach to interleukin 17</li><li>is administered by subcutaneous injection and patients may self-inject</li><li>is given at a recommended dose of 160mg every 4 weeks. However, for PsA patients with coexistent moderate to severe plaque psoriasis the recommended dose is 320mg at week 0, 4, 8, 12, 16 and every 8 weeks thereafter.</li></ul></li><li>the NICE acceptance for bimekizumab for PsA and axSpA includes the statement ‘<i>If people with the condition and their clinicians consider bimekizumab to be 1 of a range of suitable treatments (including ixekizumab and secukinumab), after discussing the advantages and disadvantages of all the options, use the least expensive.</i>’</li><li>the service plans to supply bimekizumab via a homecare arrangement</li><li>evidence for PsA comes from BE OPTIMAL and BE COMPLETE, the †ACR50 at week 16 was:<ul style="list-style-type: none"><li>BE OPTIMAL 44% for bimekizumab, 10% for placebo and 46% for adalimumab</li><li>BE COMPLETE 43% for bimekizumab versus 7% for placebo</li></ul></li><li>evidence for axSpA comes from the BE MOBILE studies, the ‡ASAS 40 at week 16 was:<ul style="list-style-type: none"><li>BE MOBILE 1 [in non-radiographic patients] 47.7% for bimekizumab versus 21.4% for placebo</li><li>BE MOBILE 2 [in radiographic patients] 44.8% for bimekizumab versus 22.5% for placebo</li><li>in the BE MOBILE studies, uveitis events were lower in patients with bimekizumab than placebo</li></ul></li><li>cost off-set will be available as bimekizumab will be used instead of an alternative biologic therapy</li><li>the service plans to offer the most cost effective IL-17 inhibitor (secukinumab or bimekizumab) second-line after tumour necrosis factor alpha inhibitors</li></ul>	

The Group accepted the restricted local need for bimekizumab for the treatment of adults

† ACR (American College of Rheumatology) scoring system, ACR50 = 50% improvement in patients' arthritis symptoms

‡ ASAS (Assessment of SpondyloArthritis International Society) 40% improvement

**PROTECTIVE MARKING: NONE**

<b>ITEM</b>	<b>SUBJECT</b>	<b>ACTION</b>
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with PsA, active nr-axSpA or active AS outlined in SMC 2605 and SMC 2616.

**SMC 2605 - Bimekizumab 160mg solution for injection in pre-filled syringe and pre-filled pen (Bimzelx®) is routinely available in line with national guidance (SMC 2605).**

**Indication under review: alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adults who have not responded adequately to two conventional DMARDs.**

**Bimekizumab offers an additional treatment choice of in the therapeutic class of interleukin inhibitors 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. Bimekizumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which bimekizumab is indicated.**

**FTEAM**

**SMC 2616 - Bimekizumab 160mg solution for injection in pre-filled syringe and pre-filled pen (Bimzelx®) is routinely available in line with national guidance (SMC 2616).**

**Indication under review: for the treatment of adults with:**

- **active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).**
- **active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.**

**Bimekizumab offers an additional treatment choice in the therapeutic class of immunosuppressants 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. Bimekizumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which bimekizumab is indicated.**

**FTEAM**

## **5.2. SMC 2625 - DEGARELIX (PROSTATE CANCER)**

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

The Group considered the request for degarelix for the treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy, and as neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer.

The Group noted that:

- **degarelix:**
  - **is already included on the formulary for the treatment of adults with advanced hormone-dependent prostate cancer**
  - **the recommended starting dose is 240mg administered as two consecutive 120mg subcutaneous injections, then 80mg administered as one subcutaneous injection every month**
- **for neo-adjuvant use, the efficacy of degarelix in terms of prostate shrinkage was found to be non-inferior to that of goserelin plus bicalutamide. The total prostate**

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	<p>volume decreased from baseline to week 12 in both treatment groups, 36% with degarelix and 35.3% in goserelin.</p> <ul style="list-style-type: none"><li>the effect of degarelix in combination with radiotherapy is based on an indirect comparison to the gonadotropin releasing hormone (GnRH) agonists efficacy data by using the clinical efficacy surrogate endpoints; testosterone suppression and prostate specific antigen (PSA) reduction demonstrating non-inferiority to GnRH agonists and indirectly establish efficacy</li><li>since degarelix does not induce a testosterone surge it is not necessary to add an anti-androgen as surge protection at initiation of therapy as is required with GnRH agonists</li><li>the service stated that treatment will be given for 6 months or 24 months depending on the indication. This duration is based on various trials and combinations, the local approach based on evidence is 6 months in intermediate-risk and 2 years in high-risk (can reduce to 18 months in certain high risk).</li><li>the service plans to treat patients with intermediate-risk only if they have severe vascular disease and androgen deprivation therapy is required</li><li>the service states the advantages of degarelix compared to GnRH agonists are that degarelix may be a better option for patients needing rapid response (e.g., ureteric obstruction, significant urinary outflow obstruction) and for patients with significant vascular disease. Degarelix will also be used where castrate levels of testosterone are not achieved by a GnRH agonist.</li><li>the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of degarelix</li></ul>	

The Group accepted the restricted local need for degarelix for the treatment of adults with high-risk localised and locally advanced hormone dependent prostate cancer as outlined in SMC 2625.

**SMC 2625 - Degarelix 80mg, 120mg injection (Firmagon®) is routinely available in line with national guidance (SMC 2625).**

**Indications under review: in adults:**

- for the treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy**
- as neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer**

**Degarelix offers an additional treatment choice in the therapeutic class of gonadotrophin releasing hormone (GnRH) antagonist/agonist in this setting. 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 8d - treatment may be initiated in community on the recommendation of a consultant/specialist.**

FTEAM

**5.3. SMC 2441 - TRIFAROTENE (ACNE VULGARIS)**

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

The Group considered the request for trifarotene for the cutaneous treatment of acne vulgaris of the face and/or the trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present.

The Group noted that:

- trifarotene:
  - is a topical cream with retinoid activity
  - is applied as a thin layer to the affected areas of the face and/or trunk once a day, in the evening on clean dry skin. It is recommended that the physician assesses

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	<p>the continued improvement after three months of treatment.</p> <ul style="list-style-type: none"><li>is included in the Primary Care Dermatology Society (PCDS) Acne vulgaris guidelines</li><li>evidence comes from the PERFECT studies:<ul style="list-style-type: none"><li>in PERFECT 1 (after 12 weeks) the Investigator Global Assessment (IGA) was 29.4% for trifarotene vs 19.5% for placebo. The mean change in inflammatory lesion count was -19 for trifarotene vs -15.4 for placebo, and the mean change in non-inflammatory lesion count was -25 for trifarotene vs -17.9 for placebo</li><li>in PERFECT 2 the IGA was 42.3% for trifarotene vs 19.5% for placebo. The mean change in inflammatory lesion count was -24.2 for trifarotene vs -18.7 for placebo, and the mean change in non-inflammatory lesion count was -30.1 for trifarotene vs -21.6 for placebo.</li></ul></li><li>in a 52 week, non-comparative trial, the overall treatment success was 57.9%</li><li>the service states treatment can be continued up to six months</li><li>cost off-set will be available as patients would have received an alternative topical treatment</li></ul>	

Primary Care members confirmed that they refer to different guidance, mainly NICE and PCDS, and that the formulary entry should highlight the place of trifarotene in the treatment pathway.

FTEAM

**SMC 2441 - Trifarotene 50microgram/g cream (Aklief®) ▼ is routinely available in line with national guidance (SMC 2441).**  
**Indication under review: for the cutaneous treatment of acne vulgaris of the face and/or the trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present.**  
**Trifarotene provides an additional treatment choice in the therapeutic class of topical retinoids.**  
**It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.**

FTEAM

**6. FORMULARY REVIEW**

**6.1. ACNE PATHWAY (TOPICAL TREATMENTS)**

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

Members reviewed the current formulary choice of topical treatments for acne.

The Group noted that:

- for the five quarters Q2 2022 to Q2 2023 four products account for ~70% of prescriptions
- combination benzoyl peroxide plus clindamycin was prescribed most frequently (25 to 29% of prescriptions), with single agent clindamycin, single agent benzoyl peroxide and adapalene plus benzoyl peroxide all similar at 15 to 18%
- erythromycin with zinc acetate prescribing was stable at ~ 7% of prescriptions
- tretinoin with erythromycin (Aknemycin® Plus solution) had the lowest prescribing figure at ~ 0.3% of prescriptions
- topical isotretinoin as a single agent or fixed combination product [isotretinoin plus erythromycin] is no longer available and will be noted as discontinued on the formulary

FTEAM

Members supported changes to:

- the single agent topical antibiotic choices, changing topical clindamycin to non-formulary (because combination products are preferred), with topical erythromycin remaining on formulary, restricted, with a note that it may be an option in pregnancy/breastfeeding
- the single agent azelaic acid choices, noting Skinoren® 20% cream as the preferred

## PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	choice because it is more cost-effective than Finacea® [£4.49 versus £7.48 for 15% gel (both 30g)]. Finacea® remains on the formulary for rosacea.	FTEAM
	The Group did not support including tretinoin with erythromycin, as Aknemycin® Plus solution (0.025% and 4%), on the formulary. It has a very small prescribing rate and is only included in the PCDS guidance, where it is noted as an 'other option', i.e., third-line for mild to moderate papular/pustular acne.	FTEAM
	The Formulary Team will investigate if ScriptSwitch can be utilised to direct prescribing away from single-agent clindamycin.	FTEAM

### 6.2. FORMULARY UPDATES

Dr Culligan declared a personal, non-specific interest in Takeda and took part in decision-making.

Mr Paterson declared a personal, non-specific interest in AstraZeneca UK Limited and took part in decision-making.

The Group reviewed the Formulary Team's summary document highlighting a medicine that is not requested locally and some discontinued medicines.

#### PATROMER SORBITEX CALCIUM

The Group noted that:

- following abbreviated submissions reviewed by the SMC executive, patiromer sorbitex calcium (Veltassa®) was accepted for restricted use in NHS Scotland:
  - for the treatment of adults with hyperkalaemia (defined as a serum potassium of >6.0mmol/L) with chronic kidney disease (CKD) stage 3b to 5 and/or heart failure, who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor (RAASi) therapy to maintain a clinically acceptable serum potassium level (normokalaemia) [SMC 2381, August 2021]
  - in the emergency care setting for the treatment of acute, life-threatening hyperkalaemia alongside standard care [SMC 2586, April 2023]
- the Renal Service does not wish to apply for formulary inclusion at this time as the preferred treatment is sodium zirconium cyclosilicate (Lokelma®).

The Group supported the service's position and recorded this medicine and indications as 'Not routinely available as there is a local preference for alternative medicines'.

**SMC 2381 - Patiromer sorbitex calcium 8.4g, 16.8g powder for oral suspension (Veltassa®) is not routinely available as there is a local preference for alternative medicines.**

**Indication under review: treatment of hyperkalaemia in adults.**

**SMC restriction: patients with hyperkalaemia (defined as a serum potassium of >6.0mmol/L) with chronic kidney disease (CKD) stage 3b to 5 and/or heart failure, who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor (RAASi) therapy to maintain a clinically acceptable serum potassium level (normokalaemia).**

**Patiromer sorbitex calcium offers an additional treatment choice in the therapeutic class of non-absorbed cation-exchange compounds that act as selective potassium binders.**

**Not routinely available as there is a local preference for alternative medicines.**

FTEAM

**SMC 2568 - Patiromer sorbitex calcium 8.4g, 16.8g powder for oral suspension (Veltassa®) is not routinely available as there is a local preference for alternative medicines.**

**Indication under review: treatment of hyperkalaemia in adults.**

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	<p><b>SMC restriction: in the emergency care setting for the treatment of acute, life-threatening hyperkalaemia alongside standard care.</b></p> <p><b>Patiromer sorbitex calcium offers an additional treatment choice in the therapeutic class of non-absorbed cation-exchange compounds that act as potassium binders. SMC has previously issued advice for patiromer sorbitex calcium for the treatment of hyperkalaemia in adults with chronic kidney disease stage 3b to 5 and/or heart failure, who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor therapy to maintain a clinically acceptable serum potassium level (normokalaemia) (SMC 2381). This advice remains valid.</b></p> <p><b>Not routinely available as there is a local preference for alternative medicines.</b></p>	<p><b>FTEAM</b></p>

DISCONTINUATIONS

The Group supported the Formulary Team's suggested action to amend the formulary entries to note that the:

- product is withdrawn from use/discontinued for:
  - bezlotoxumab 25mg/mL conc. for soln for infusion (Zinplava®)
  - capsaicin 0.025% cream (Zacin®) and capsaicin 0.075% cream (Axsain®)
  - ethinylestradiol 10micrograms, 50micrograms, 1mg tablets
  - exenatide 5micrograms, 10micrograms soln for injection (Byetta®)
- conditional marketing authorisation is withdrawn/revoked:
  - mobocertinib 40mg hard capsules (Exkivity®)
  - crizanlizumab 10mg/mL conc. for solution for infusion (Adakveo®)

**FTEAM**

A member reported that the Pain Clinic is recommending capsaicin cream which has to be sourced as a special. The Formulary Team will confirm the cost of the specials products and liaise with the Medicines Management and Pain Teams to confirm the need or otherwise for capsaicin cream.

**FTEAM**

**6.3. H.PYLORI INFECTION TREATMENT UPDATE**

Ms Doney summarised information from the Gastroenterology Service regarding update of the *H.Pylori* treatment regimens.

Ms Doney confirmed that:

- the local *H.Pylori* treatment guidance has been reviewed by the Gastroenterology Service in collaboration with the Antimicrobial Management Team (AMT)
- supply issues with bismuth tablets mean it is no longer included in the treatment regimens, although stocks may improve at the end of 2024
- the main changes to the guidance are:
  - updated prescribing points
  - minor change to first-line choices with the treatment duration for first-line non-penicillin allergy increased to 14 days (from 7)
  - second-line non-penicillin allergy is now dual therapy (previously quadruple bismuth-containing regimen)
  - new treatment option for penicillin-allergy second-line (triple therapy with PPI plus levofloxacin plus clarithromycin)

Members discussed the potential changes and were supportive of the update, but queried the new treatment option for penicillin-allergy second-line, especially in light of the strengthened Medicines and Healthcare products Regulatory Agency (MHRA) recommendation.

In January 2024 the MHRA advised that systemic fluoroquinolones must now only be prescribed when other commonly recommended antibiotics are inappropriate.

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	Members supported update of the <i>H. Pylori</i> treatment regimens but requested further information, including clarification that the strengthened MHRA advice was considered as part of the update, and that systemic fluoroquinolones are being used when other antibiotics, that are commonly recommended for the infection, are inappropriate.	
	Pending information from the service member agreed to update the current guidance in line with the request but withhold publication of the new second-line treatment regimen.	FTEAM
	<b>6.4. Ivermectin (unlicensed product, scabies)</b>	
	This item was deferred to a future meeting.	
	<b>6.5. Carbon footprint for inhalers</b>	
	Mrs Standen confirmed that the Formulary Team is working with the Respiratory Managed Clinical Network to develop a colour coded footprint icon that will be included on the formulary entries for inhalers. This will help patients and prescribers to see the carbon footprint of different inhalers.	
	This is in development and will be brought to the March meeting.	FTEAM
<b>7.</b>	<b>PUBLISHED ADVICE</b>	
	<b>7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED FEBRUARY 2024</b>	
	The Group noted the SMC advice published February 2024.	
	Following publication of the negative SMC recommendation, for cabozantinib (Cabometyx <sup>®</sup> ) SMC 2590, and the non-submission statements, for ravulizumab (Ultomiris <sup>®</sup> ) SMC 2657 and SMC 2658, these medicines will not be included on the Grampian Joint Formulary for the indications in question.	FTEAM
	The following SMC accepted medicines have not been processed within a 60-day timescale:	
	<ul style="list-style-type: none"><li>• SMC 2623 difelikefalin (Kapruvia<sup>®</sup>)▼ (submission expected)</li><li>• SMC 2598 dupilumab (Dupixent<sup>®</sup>) (submission received)</li><li>• SMC 2609 loncastuximab tesirine (Zynlonta<sup>®</sup>)▼ (submission received)</li><li>• SMC 2592 secukinumab (Cosentyx<sup>®</sup>) (submission expected)</li></ul>	
	Local advice for these medicines and indications will be included in the February 2024 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'.	FTEAM
	<b>7.2. NATIONAL CANCER MEDICINES ADVISORY GROUP ADVICE PUBLISHED JANUARY 2024</b>	
	The Group noted the NCMAG provisional advice issued January 2024.	
	Following publication of the not supported recommendation for pazopanib (Votrient <sup>®</sup> ) NCMAG 112, this medicine will not be included on the Grampian Joint Formulary for the indication in question.	FTEAM
	The following NCMAG supported medicine has not been processed within a 60-day timescale:	
	<ul style="list-style-type: none"><li>• NCMAG 111 sunitinib (submission expected)</li></ul>	
	Local advice for this medicine and indication will be included in the February 2024 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'.	FTEAM

ITEM SUBJECT

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED FEBRUARY 2024

The Group noted the SMC provisional advice issued February 2024.

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

FTEAM

9. OTHER BUSINESS

None.

10. DOCUMENTS FOR INFORMATION

Items 10.1 (Drug Safety Update January 2024), 10.2 (Medicine Guidelines and Policies Group (MGPG) minute July 2023) and 10.3 (Grampian Primary Care Group minute November 2023) were noted.

11. AOCB

CODEINE LINCTUS TO BE RECLASSIFIED TO A PRESCRIPTION-ONLY MEDICINE

Ms Doney reported that the MHRA has issued a press release confirming that codeine linctus will be reclassified to a prescription-only medicine due to the risk of abuse, dependency and overdose.

The change will not affect the formulary as it does not include cough suppressants, however the press release has been shared with the Palliative Care pharmacist as there may be some use in palliative care.

CONFLICTS OF INTEREST

Members discussed the difficulty of identifying a conflict of interest where one company is owned in part or full by another or other pharmaceutical companies.

DATE OF NEXT MEETING

Tuesday 19 March 2024 starting at 14.30 via Microsoft Teams

CHAIR'S SIGNATURE



DATE 19 MARCH 2024