NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 20 October 2020 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Mr C Rore	
Ms F Doney	Professor J McLay	
Dr L Elliot (Chair)		
Dr J Fitton		
Ms M Galvin		
Mrs L Harper (from item 2)		
Dr M Metcalfe (from item 8.1)		
Mrs L Montgomery		
Mrs K Neave		
Mr M Paterson		
Mr R Sivewright		
Dr A Sun (from item 4.3)		

IN ATTENDANCE
Ms Caitlin Wilkinson, Formulary Team administrator.

ITEM	SUBJECT	ACTION
	The Chair welcomed members, opened the meeting and noted that a quorum was present.	
1.	**APOLOGIES**	
	Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 15 SEPTEMBER 2020**	
	The Group accepted the draft note of the meeting subject to minor typographical changes. The corrected final approved minute will be in the public domain within 21 days of approval.	**FD**
3.	**PRESENTATION - NONE**	
4.	**MATTERS ARISING**	
	4.1. ACTION LOG	
	The Action log was noted. No additional items were identified that should have been included on the agenda.	
	4.2. FORMULARY GROUP REGISTER OF INTERESTS	
	The Group reviewed and approved the Formulary Group Register of interests' intranet web space.	
	4.3. FG1SMC 2273 - ANDEXANET ALFA (REVERSAL OF RIVAROXABAN AND APIXABAN)	
	There were no declarations of interest recorded in relation to this product. At the September meeting, members discussed the request to include andexanet alfa on formulary for the reversal of the direct factor Xa (FXa) inhibitors apixaban and rivaroxaban. Ms Doney confirmed that: • a paper will be submitted to the November meeting of the Grampian Area Drug and Therapeutics Committee (GADTC) • colleagues in Glasgow are developing a guideline that will include reversal for patients	

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on edoxaban.
Lothian consultants are linking with haematologists in Glasgow, and are keen to have guidance in place before introducing andexanet alfa into practise.
Colleagues in Tayside are discussing use at their October Medicines Advisory Group meeting.

- there may have been some discussion about a national consensus statement that would include edoxaban. However, there is not a timeline for its production and it is not clear that a national statement will be progressed.
- andexanet alfa is now stocked within the managed service
- andexanet alfa's licence limits use - 'restricted to hospital use only'

The Group considered that as andexanet alfa is now stocked within the managed service, inclusion on formulary [in line with SMC advice] would help progress publication of a local protocol to support introduction. The Group supported formulary inclusion, as outlined in SMC 2273, pending discussion of the wider issues identified previously.

The Group accepted the restricted local need for andexanet alfa for adults treated with apixaban or rivaroxaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding, as outlined in SMC 2273.

SMC 2273 – Andexanet alfa 200mg powder for solution for infusion (Ondexxya®) ▼ is routinely available in line with national guidance, on an interim basis subject to ongoing evaluation and future reassessment (SMC 2273).
Indication under review: for adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.
In an open-label single-arm study andexanet alfa reduced anti-FXa activity and improved haemostatic efficacy in adults with major bleeds.
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 8a – licensed for hospital use only. Restricted to hospital use only. **FTEAM**

4.4. PRIADEL® 200MG, 400MG DISCONTINUATION - UPDATE

The Chair confirmed that the decision to discontinue Priadel® is currently on hold while Essential Pharma and the Department of Health and Social Care (DHSC) hold pricing discussions.
There is no longer an urgent need to implement system-wide switching of patients. However, the specialist service will continue to work on potential switch options, in case the pricing discussions stall.

Essential Pharma has confirmed supplies of Priadel® 200mg and 400mg tablets are sufficient to meet current UK demand and is working to ensure further stocks are available to maintain supply after April 2021.

The Formulary Team will keep a watching brief on the situation. **FTEAM**

5. FORMULARY GROUP DECISIONS SEPTEMBER 2020 - PUBLISHED 29 SEPTEMBER 2020

5.1. FORMULARY GROUP DECISIONS SEPTEMBER 2020

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

6. NETFORMULARY/FORMULARY REVIEW

6.1. DISCONTINUED ITEM - DIAMORPHINE HYDROCHLORIDE 720MICROGRAMS/ACTUATION, 1600MICROGRAMS/ACTUATION NASAL SPRAY (AYENDI®)

ITEM	SUBJECT	ACTION

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

Ms Doney reported that diamorphine hydrochloride 720micrograms/actuation, 1600micrograms/actuation nasal spray (Ayendi®) has been discontinued by the marketing authorisation holder (Wockhardt UK Ltd) due to manufacturing issues.

Ayendi® nasal spray was accepted to formulary in August 2017, restricted to the Paediatric Emergency Department as a replacement for the off-label use of intranasal diamorphine for severe pain in children (in emergency setting).

The formulary will be updated to reflect the withdrawal.

SMC 1172/16 - Diamorphine hydrochloride 720micrograms/actuation, 1600micrograms/actuation nasal spray (Ayendi®) is now withdrawn from use/discontinued.
Indication: treatment of acute severe nociceptive pain in children and adolescents in a hospital setting.
This medicine is now withdrawn from use/discontinued. **FTEAM**

6.2. SMC 2211 - IMIQUIMOD 3.75% CREAM (ZYCLARA®) (LARGE FIELD ACTINIC KERATOSIS)

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

The Dermatology service has confirmed that it does not wish to add this medicine to the formulary at this time.

Ms Davie highlighted the potential for confusion with the 3.75% and 5% preparations [5% cream is currently included on formulary].

The Formulary Team will check the prescribing status of imiquimod 3.75% cream, and confirm if a ScriptSwitch message should be implemented to highlight the non-formulary status of Zyclara®. **FTEAM**

SMC 2211 - Imiquimod 3.75% cream (Zyclara®) is not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time.
Indication: for the topical treatment of clinically typical, non-hyperkeratotic, non-hypertrophic, visible or palpable actinic keratosis of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate.
SMC restriction: for the treatment of large field actinic keratosis (>25cm^2).
It was classified - Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI). **FTEAM**

6.3. ARSENIC TRIOXIDE (TRISENOX®)

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

It was reported that the specialist service has confirmed that it has moved to the new higher strength arsenic concentrate for solution for infusion [moved from 1mg/mL to 2mg/mL].

The Group noted the local need for arsenic in the management of acute promyelocytic leukaemia (APL) and the preferred preparation is now the 2mg/mL preparation.
The 1mg/mL preparation will be noted as non-formulary.

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	Arsenic trioxide 2mg/mL concentrate for solution for infusion (Trisenox®) is routinely available in line with local guidance. **Indication: for induction of remission, and consolidation in adult patients with:** • **newly diagnosed low-to-intermediate risk acute promyelocytic leukaemia (APL) (white blood cell count, ≤10 x 10^3/µl) in combination with all-*trans*-retinoic acid (ATRA)** • **relapsed/refractory acute promyelocytic leukaemia (APL) (previous treatment should have included a retinoid and chemotherapy)** **characterised by the presence of the t(15;17) translocation and/or the presence of the promyelocytic leukaemia/retinoic-acid-receptor-alpha (PML/RAR-alpha) gene.** **The response rate of other acute myelogenous leukaemia subtypes to arsenic trioxide has not been examined.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.** **Treatment must be administered under the supervision of a physician who is experienced in the management of acute leukaemias, and the special monitoring procedures described in section 4.4 of the SmPC must be followed.**	**FTEAM**
	Arsenic trioxide 1mg/mL concentrate for solution for infusion is not routinely available as there is a local preference for alternative medicines. **Indication: for induction of remission, and consolidation in adult patients with:** • **newly diagnosed low-to-intermediate risk acute promyelocytic leukaemia (APL) (white blood cell count, ≤10 x 10^3/µl) in combination with all-*trans*-retinoic acid (ATRA)** • **relapsed/refractory acute promyelocytic leukaemia (APL) (previous treatment should have included a retinoid and chemotherapy)** **characterised by the presence of the t(15;17) translocation and/or the presence of the promyelocytic leukaemia/retinoic-acid-receptor-alpha (PML/RAR-alpha) gene.** **It was classified - Not routinely available as there is a local preference for alternative medicines.**	**FTEAM**
7.	**OTHER BUSINESS**	
	7.1. FORMULARY GROUP REPORT FOR THE GADTC Ms Doney confirmed that the Grampian Area Drug and Therapeutics Committee (GADTC) has requested an annual report for 2019/20. Due to the short turnaround expected the report will be quite brief. A draft of the report will be shared with members before it is submitted for the 23/10/2020 deadline.	**FD**
8.	**NEW PRODUCT REQUESTS**	
	8.1. FG1SMC 2250 - USTEKINUMAB (ULCERATIVE COLITIS) There were no declarations of interest recorded in relation to this product. The Group considered the request for ustekinumab for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies. The Group noted: • ustekinumab: ▪ is already included on the formulary for plaque psoriasis (12 years +), and for adults with psoriatic arthritis or Crohn's disease ▪ is the first interleukin inhibitor licensed for use in ulcerative colitis, so provides a different mode of action to the other biologic agents [licensed for ulcerative colitis]	

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- is initiated with a single intravenous dose, followed by subcutaneous injections 8 weeks later. After this, patients may be dosed every 8 weeks or 12 weeks according to clinical judgement.
- [for this indication] would become an alternate third-line option [to vedolizumab] for adults with moderately to severely active ulcerative colitis
- is another biologic available in Gastroenterology (GI) as a subcutaneous preparation

- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ustekinumab
- if used third-line instead of vedolizumab there is cost offset available. However, costs will ultimately increase as patients move through the different biologic treatment options, increasing the potential length of time on [biologic] treatment.
- biologic treatment options have the potential to delay or defer the need for surgery
- compared to other biologic agents, ustekinumab has the lowest frequency of maintenance administration which may be an advantage for some patients
- the subcutaneous route of administration in the maintenance phase of treatment may offer benefits to patients and the service [although all biologics licensed for GI indications are available as subcutaneous injections]

Ms Doney confirmed that the questions posed to the service remain unanswered, but the Formulary Team will endeavour to get replies and update at a future meeting. **FTEAM**

The Group accepted the restricted local need for ustekinumab for the treatment of adult patients with moderately to severely active ulcerative colitis, in line with SMC 2250.

SMC 2250 - Ustekinumab 130mg concentrate for solution for infusion, 90mg solution for injection in prefilled syringe, 45mg solution for injection (vials) (Stelara®) is routinely available in line with national guidance (SMC 2250).
Indication under review: for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.
In a phase III study in patients with moderate to severe ulcerative colitis who had failed prior therapy, clinical remission was achieved by a significantly greater proportion of patients who received ustekinumab compared with placebo.
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.
Ustekinumab is intended for use under the guidance and supervision of physicians experienced in the diagnosis and treatment of conditions for which ustekinumab is indicated. **FTEAM**

Biological medicines, including biosimilar medicines, should be prescribed by both generic and brand name and the trade name and batch number should be recorded on the patient's prescription, case record or other appropriate clinical system.

8.2. FG1SMC 2215 – ABIRATERONE ACETATE (HIGH RISK MHSPC)

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

The Group considered the request for abiraterone acetate with prednisolone (or prednisone) for the treatment of newly diagnosed high-risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT).

Ms Galvin confirmed that:

- abiraterone acetate is prescribed with prednisolone [AA-P]. The combination is currently included on the formulary, in line with SMC advice, for metastatic castration resistant prostate cancer (mCRPC).
- this request moves use earlier in the treatment pathway (when men are still hormone sensitive)
- [for this indication] AA-P would be preferred to off-label use of the immunosuppressive agent docetaxel. AA-P provides a more favourable adverse effect profile with possible progression-free survival benefit. In the context of COVID-19, with minimising risk to patients and trying to keep patients out of hospital AA-P would be the preferred treatment option.
- if used in the mHSPC setting, AA-P (or enzalutamide) would not be used in the mCRPC setting
- there is a shared care arrangement (SCA) in place for the mCRPC population. If the formulary request is accepted, the SCA will be updated to include the high-risk mHSPC population.
- NCMAG published interim guidance for AA-P use in low-risk mHSPC. This is off-label use and patient numbers are expected to be small. Off-label use would not be included on the SCA, and monitoring for low-risk patients will remain within the specialist service.

The Group noted:

- AA-P for high-risk mHSPC:
  - is used in combination with ADT
  - was accepted for use in NHS Scotland following the output from the PACE process, and application of SMC modifiers
  - meets SMC orphan equivalent criteria
  - treatment should continue until progression or until the patient can no longer tolerate treatment [median duration of treatment with AA-P + ADT was 25.8 months]
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of treatment
- the current SCA is not a 'full' shared-care arrangement. The acute service prescribes AA/AA-P and Primary Care monitors patients.
- the additional pressure on Primary Care related to the extension of use to include the high-risk mHSPC population [monitoring visits]
- there will be a peak of use in the period when both mCRPC and mHSPC populations are receiving treatment
- use in mHSPC patients represents a new cost to the Board. Deferred cost offset is available, as patients receiving AA-P in the mHSPC setting will not receive treatment in the mCRPC setting.
- the prednisolone dose is different for the mCRPC and mHSPC indications, 10mg daily and 5mg daily respectively

Members raised concerns about the monitoring capacity in Primary Care, noting the extra risks of COVID-19 and extra time required for cleaning rooms etc. Some practices and/or community hubs may not have the capacity to take on additional monitoring.

The Group accepted the restricted local need for abiraterone acetate with prednisone or prednisolone for the treatment of newly diagnosed high-risk mHSPC in adult men in combination with ADT, as outlined in SMC 2215.

Acceptance is subject to confirmation that:

- there is general agreement to move monitoring visits for high-risk mHSPC patients to Primary Care, and Primary Care has the capacity to manage the monitoring visits [accepting that individual practices may not have the capacity to take on additional

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	monitoring]	FD
	• update of the SCA - only to include high-risk mHSPC patients; clearly differentiating the different prednisolone dose for the mCRPC and mHSPC populations	MG
	• NCMAG use is outwith the scope of the SCA	MG
	Until the local implementation plans are in place, monitoring for high-risk mHSPC patients will be managed by the specialist service.	MG
	SMC 2215 - Abiraterone acetate (Zytiga®) is routinely available in line with national guidance (SMC 2215). **Indication under review: abiraterone acetate with prednisone or prednisolone for the treatment of newly diagnosed high-risk metastatic hormone sensitive prostate cancer in adult men in combination with androgen deprivation therapy.** **Abiraterone acetate in combination with prednisone and androgen deprivation therapy demonstrated superiority over androgen deprivation therapy alone for improving progression-free survival and overall survival.** **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. This medicinal product should be prescribed by an appropriate healthcare professional.**	FTEAM

8.3. FG1 431/20 - MOVIPREP® (IN COMBINATION WITH PREOPERATIVE OAB FOR ELECTIVE COLORECTAL SURGERY)

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

The Group considered the request from the Colorectal Surgeons for the preoperative use of a mechanical bowel preparation (MBP) with oral antibiotics (OABs) [in addition to induction prophylactic intravenous antibiotics] to reduce surgical site infection (SSI) for adults undergoing elective colorectal resection.

The Group noted that:

- moderate quality evidence suggests that preoperative OABs combined with MBP reduces the risk of SSI in adults undergoing elective colorectal surgery
- there are no cost-effectiveness data. However, the proposed regimen is a simple short treatment course (1-day), and the individual components are inexpensive.
- patient numbers are in the hundreds of cases per year, and the overall budget impact is relatively small
- preoperative OABs plus MBP to reduce SSI in elective colorectal cancer, is supported by international guidelines [World Health Organisation], and the regimen has been implemented by other Health Boards in Scotland
- Moviprep® is requested as the preferred MBP, as it is potentially less dehydrating, better tolerated and easier for patients to take (lower volume)
- the Colorectal Service in ARI is ready to implement the change immediately, no service developments are needed to support introduction
- use will be subject to regular audit, including SSI rates, *Clostridium difficile* and multi-drug resistant organism infection rates (before and after introduction of the intervention)
- the audit data will be shared with the Antimicrobial Management Team six months after introduction to monitor for any unintended consequences

The Group agreed that preoperative OABs combined with MBP should be used to reduce the risk of SSI in adult patients undergoing elective colorectal surgery. The Group accepted the Colorectal Surgeons' request to include Moviprep® on the formulary as the

preferred MBP for this indication.

Moviprep® powder for oral solution is routinely available in line with local guidance.
Indication under review: in combination with preoperative oral antibiotics prior to elective colorectal surgery in adults.
It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. **FTEAM**

8.4. FG1SMC 2251 - NERATINIB (EARLY-STAGE HORMONE RECEPTOR POSITIVE HER2-OVEREXPRESSED/AMPLIFIED BREAST CANCER)

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

The Group considered the request for neratinib for the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago.

Ms Galvin confirmed that:

- neratinib:
  - is the first medicine licensed for extended adjuvant treatment in hormone receptor positive and HER-2 positive breast cancer patients
  - represents a new and additional cost to the service, no cost offset is available
  - requires regular liver function test monitoring, and increased cardiac monitoring for some patients
- diarrhoea is a very common and early side effect of treatment
- monitoring will be managed by the specialist service
- there will be a peak of use in the first year when both incident and prevalent patient groups are eligible for treatment. This will level out in year two when only incident patients will be eligible [ExteNET mean treatment duration <1 year]
- ExteNET did not include people who received adjuvant pertuzumab (+ trastuzumab) or Kadcyla®, or those who had a pathological complete response (no sign of residual invasive disease in the breast or axilla) after chemotherapy-based neoadjuvant treatment
- pertuzumab and Kadcyla® used in the adjuvant setting have recently been accepted by the SMC. National discussions are ongoing regarding where neratinib will sit within the pathway in relation to the recent SMC approvals. The changes will be reflected in the regional Clinical Management guideline.

The Group accepted the restricted local need for neratinib for the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago, in line with SMC 2251.

Ms Galvin will feedback the outcome of the national discussions in due course. **MG**

SMC 2251 - Neratinib 40mg film-coated tablets (Nerlynx®) ▼ is routinely available in line with national guidance (SMC 2251).
Indication under review: for the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago.
In the relevant subgroup of a phase III study neratinib, given less than one year after adjuvant trastuzumab-based therapy, improved invasive disease-free survival in patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer compared with placebo.
This advice applies only in the context of an approved NHS Scotland Patient

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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 physician experienced in the administration of anti-cancer medicinal products. **FTEAM**

8.5. FG1SMC 2288 – SODIUM ZIRCONIUM CYCLOSILICATE (HYPERKALAEMIA IN ADULT PATIENTS)

Mr Paterson and Dr Fitton declared personal, non-specific interests in Astra Zeneca, and took part in the discussion.

The Group discussed the request for sodium zirconium cyclosilicate for the treatment of hyperkalaemia in adult patients in line with SMC 2288.

The Group noted:

- sodium zirconium cyclosilicate:
  - was accepted for restricted use, following a resubmission, for a subgroup of its licence - positioned for use to prevent dose reduction or discontinuation of renin-angiotensin-aldosterone system inhibitor (RAASi) therapies in hyperkalaemic patients (serum potassium >6.0mmol/L) with CKD (stage 3b to 5) and/or heart failure.
  - is considered high in sodium
  - should be stopped if RAASi therapies are no longer suitable
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of sodium zirconium cyclosilicate
- the SMC did not assess the evidence for the use of sodium zirconium cyclosilicate in chronic haemodialysis patients
- the lack of long-term data despite this potentially being a chronic treatment
- the risk of patients being lost to follow-up if treatment is transferred to Primary Care without clear processes/supporting information. Would Primary Care clinicians be expected to adjust treatment?
- the risk of patients continuing treatment when RAASi therapies were stopped

The Group was unclear of the long-term monitoring requirements, and questioned if there was evidence of greater benefit from being able to continue RAASi therapies rather than stabilise patients off RAASi therapies.
Members expressed a concern about the lack of experience in Primary Care to support the safe implementation of sodium zirconium cyclosilicate.

The Group felt that more information was required, and requested that a Nephrologist attend a future meeting to discuss the submission and processes required to support the safe introduction of sodium zirconium cyclosilicate. **FTEAM**

SMC 2288 - Sodium zirconium cyclosilicate 5g, 10g powder for oral suspension (Lokelma®) ▼ is not routinely available as the ADTC is waiting for further advice from local clinical experts.
Indication under review: treatment of hyperkalaemia in adult patients.
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)
Sodium zirconium cyclosilicate, compared with placebo, reduced serum potassium in two and four-week studies in adults with hyperkalaemia. In an uncontrolled one-year study sodium zirconium cyclosilicate produced normal serum potassium in a proportion of adults with hyperkalaemia.

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	This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower. **Not routinely available as the ADTC is waiting for further advice from local clinical experts.**	**FTEAM**

8.6. FG1SMC 2301 AND FG1SMC 2304 – DARATUMUMAB SUBCUTANEOUS INJECTION (MULTIPLE MYELOMA)

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

The Group discussed the two abbreviated SMC advice documents for daratumumab subcutaneous injection, SMC 2301 and SMC 2304.

Ms Doney confirmed that:

- daratumumab, as the intravenous formulation, is included on the formulary for the same indications
- the abbreviated SMC advice relates to a new formulation – subcutaneous injection
- no significant cost implications have been identified
- a subcutaneous preparation could be beneficial for patients and the service

The Group accepted the restricted local need for daratumumab subcutaneous injection as outlined in SMC 2301 and SMC 2304.

SMC 2301 - Daratumumab 1,800mg solution for subcutaneous injection (Darzalex®)
▼ is routinely available in line with national guidance (SMC 2301).
Indication under review: in combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received one prior therapy only.
Following a submission under the orphan medicine process, SMC has previously accepted daratumumab 20mg/mL concentrate for solution for infusion for restricted use in combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received one prior therapy only (SMC 2180).
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.
Daratumumab should be administered by a healthcare professional, and the first dose should be administered in an environment where resuscitation facilities are available. **FTEAM**

SMC 2304 - Daratumumab 1,800mg solution for subcutaneous injection (Darzalex®)
▼ is routinely available in line with national guidance (SMC 2304).
Indication under review: as monotherapy, as a fourth-line treatment option in adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.
Following a resubmission under the end of life and orphan medicine process, SMC has previously accepted daratumumab 20mg/mL concentrate for solution for infusion for restricted use as a fourth-line treatment option (SMC 1205/17).
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.

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	Daratumumab should be administered by a healthcare professional, and the first dose should be administered in an environment where resuscitation facilities are available.	**FTEAM**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – OCTOBER 2020

The Group noted the SMC provisional advice issued October 2020.

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS – OCTOBER 2020

The Group noted the SMC advice published October 2020.

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

- SMC 2248 avelumab (Bavencio®) ▼
- SMC 2158 budesonide (Jorveza®) (submission expected)
- SMC 2290 carfilzomib (Kyprolis®) ▼ (submission expected)
- SMC 2259 ibrutinib (Imbruvica®) (submission received)
- SMC 2281 lenalidomide (Revlimid®) ▼ (submission received)
- SMC 2289 lenalidomide (Revlimid®) ▼ (submission expected)
- SMC 2265 siponimod (Mayzent®) ▼ (submission expected)
- SMC 2278 Vaborem® (meropenem/vaborbactam) ▼ (submission expected)

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

ULTRA-ORPHAN MEDICINES ASSESSMENT REPORTS (UMAR)

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

The Chair highlighted the SMC initial assessment report published for cerliponase alfa.

Cerliponase alfa is a medicine licensed for a very rare disease. It has been validated as 'ultra-orphan' and will be made available through the NHS in Scotland for up to three years [for the indication in question] while evidence on its effectiveness is generated – *the Scottish Government (SG) ultra-orphan pathway*.

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

SMC 2286 - Cerliponase alfa 150mg solution for infusion (Brineura®) ▼ is not routinely available in NHS Grampian.
Indication under review: for the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency.
Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI).
Cerliponase alfa must only be administered by a trained healthcare professional knowledgeable in intracerebroventricular administration in a healthcare setting. **FTEAM**

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM – OCTOBER 2020

CANAGLIFLOZIN (INVOKANA®) FILM COATED TABLETS

The European Medicines Agency (EMA) has recently amended the summary of product characteristics (SmPC) for canagliflozin to include renal outcome data from the CREDENCE study. Changes in posology are outwith remit for the SMC, the change will be discussed with the local clinicians. **FTEAM**

ITEM	SUBJECT	ACTION

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update September 2020), 12.2 (Grampian Primary Care Prescribing Group minute August 2020), 12.3 (Grampian Area Drug and Therapeutics Committee minute January 2020), and 12.4 (Grampian Area Drug and Therapeutics Committee minute March 2020) were noted.

Item 12.5 (Warfarin and other blood thinners press release)
Ms Doney highlighted the press release regarding Warfarin and other blood thinners and the safe use during COVID-19.
Ms Doney confirmed this information has been shared with colleagues in Primary Care and the Acute Service.

13. AOCB - NONE

DATE OF NEXT MEETING

Tuesday 17 November 2020 starting at 14.30 via Microsoft Teams.

CHAIR'S SIGNATURE LP Elliot **DATE 17 NOVEMBER 2020**