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

PRESENT	APOLOGIES	APPROVED
Miss R Anderson	Mrs M Galvin (Mrs Howlett deputising)	
Ms L Cameron	Mr M Paterson	
Dr V Chieng (until item 6)	Mrs S O'Beirne (Miss Anderson deputising)	
Dr D Culligan		
Ms A Davie		
Ms F Doney (Vice-Chair)		
Dr L Elliot (Chair)		
Mrs S Howlett		
Mrs G McKerron		
Mrs E Milne		
Dr K Simpson		
Mr R Sivewright (until item 5.4)		

IN ATTENDANCE
Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team.
Dr Santosh Raga, Consultant Cardiologist, for item 4.
Sarah Grant, Community Heart Failure Nursing Team Leader, Aberdeenshire CHP, for item 4.
Ms Lynne Davidson, Clinical Pharmacist Cardiology, for item 4.

ITEM	SUBJECT	ACTION

WELCOME

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

1. APOLOGIES

Apologies for absence were requested and noted.

2. MINUTE AND DECISIONS

2.1. DRAFT MINUTE OF THE MEETING HELD 18 JUNE 2024

The Chair confirmed that as the draft minute was sent the day before the meeting, members have until Friday 06 September to provide comment. **ALL**

The corrected final approved minute will be in the public domain within 21 days of final approval. **FD**

2.2. FORMULARY GROUP DECISIONS JUNE 2024 - PUBLISHED 01/07/2024

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

3. MATTERS ARISING

3.1. Action LOG

The action log was noted.

3.2. UPDATE – EPIMAX® OINTMENT, EPIMAX® PARAFFIN FREE OINTMENT

Ms Doney reported that in June, following further reports across the UK concerning eye-related injuries, Aspire Pharma Limited issued another Field Safety Notice (FSN) regarding Epimax® Ointment and Epimax® Paraffin-Free Ointment.
The FSN advised that the product labelling for Epimax® Ointment and Epimax® Paraffin-Free Ointment were amended to restrict the products to use on the body, and to not use

ITEM	SUBJECT	ACTION

the products on the face.

The formulary was updated after the June meeting, and the Medication Safety Advisor issued an NHS Grampian patient safety letter summarising the situation in July.

Item closed. **FTEAM**

4. PRESENTATION/DISCUSSION

The Chair confirmed that sodium zirconium cyclosilicate (SZC) is currently included on the formulary for the same indication but for adults with chronic kidney disease stage 3b to 5. However, it is classified as a 'hospital-only product' and this request seeks to include heart failure patients coupled with reclassification to allow prescribing in Primary Care.

Members reviewed the replies to the questions posed in the review.

The Chair welcomed Dr Raga, Mrs Grant and Ms Davidson to the meeting to discuss the request for SZC for adults with heart failure and persistent hyperkalaemia who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system (RAAS) inhibitor therapy to maintain a clinically acceptable serum potassium level.

The requestors confirmed that:

- the service does not anticipate SZC being used in many patients
- patients would be identified by the specialist heart failure nurses in the community, and discussed at the heart failure multidisciplinary team (MDT)
- it would be a MDT decision if patients would be put forward for SZC treatment, with the decision communicated from the MDT
- patients would have ongoing support from the specialist heart failure nurses in the community, and the nurses would have direct access to the cardiology heart failure consultants for advice if needed
- the service would develop guidance for the specialist heart failure nurses to enable consistent advice for patients, regardless of whether the specialist heart failure nurses were prescribers or not. The baseline guidance would allow the nurses to provide advice on dose adjustments, when appropriate to stop etc.
- not all of the specialist heart failure nurses are prescribers, so there are already requests for GPs to support prescribing for other heart failure medicines
- the proposal is that SZC would initially be supplied by the specialist heart failure nurses with support from GP colleagues, particularly for those that are not prescribers. The reasoning for this is that these patients would be seen by the specialist heart failure nurses in the community and are not [directly] under the care of the secondary care service.
- there were concerns for patient harm if the medicines have two different supply routes

Members considered that SZC is very different to the heart failure medicines that GPs are experienced using, e.g., ramipril. There will be a learning curve for this new drug, and Primary Care prescribers are not going to build up their expertise and confidence prescribing SZC with such low patient numbers.

Queries remained about the [Primary Care] capacity to undertake additional monitoring, and the spread of the specialist heart failure nurse service [across NHS Grampian] to be able to deliver the input required.

Members questioned why, with such small numbers across NHS Grampian, SZC prescribing cannot remain with the acute service, as is the case with renal patients. Ms Davidson reported that these patients are under the care of, and are regularly seen by, the renal service.

ITEM	SUBJECT	ACTION

Members noted the need for clear communication routes to allow quick access for advice when talking about a patient's potassium being raised or low.

Members considered that the proposed process was disjointed, with the blood results coming back to GPs, but the GPs are not actioning or advising on the required changes.

Members noted that different medicine supply routes are not uncommon as other service areas have drugs that can only be prescribed by the acute service.

Members agreed that the responsibility for prescribing and monitoring should be absolutely clear.

The Chair thanked Dr Raga, Mrs Grant and Ms Davidson for attending the meeting to discuss the SZC request. Dr Raga, Mrs Grant and Ms Davidson left the meeting before decision-making.

5.1 SMC 2288 - SODIUM ZIRCONIUM CYCLOSILICATE (CHRONIC HYPERKALAEMIA IN PATIENTS WITH HEART FAILURE)

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

Members agreed that SZC should be available for adults with persistent/recurrent hyperkalaemia and heart failure, and discussed the request to change the formulary classification to allow prescribing in Primary Care.

The Group noted that
- with such low patient numbers GPs will not have the knowledge and information [about prescribing SZC] to be able to deal with queries
- a request for a prescription from a non-prescriber can be refused, and the ultimate responsibility lies with the prescriber

Members acknowledged the concern for patient safety if RAAS inhibitor therapy was stopped and SZC continued. However, members noted this risk applied equally to treatment being stopped/changed in Primary Care or by other service areas in the hospital.

Members discussed if the linked prescribing of SZC and RAAS inhibitor therapy could be recorded on primary care prescribing systems, and queried if SZC prescribing triggered messages for prescribers.

The Group considered SZC a highly specialist medicine, and discussed the potential for moving maintenance phase prescribing into Primary Care. However, concerns remain around therapeutic escalation, the arrangements for long-term monitoring and review, and the risk of patients continuing treatment when RAAS inhibitor therapies are stopped.

The Group accepted the restricted local need for SZC for a restricted group of adults with persistent/recurrent hyperkalaemia and heart failure. The Group agreed that, at this time, prescribing and monitoring should remain within the managed service (Cardiology and/or Renal).

SMC 2288 - Sodium zirconium cyclosilicate 5g, 10g powder for oral suspension (Lokelma®) is routinely available in line with local guidance.
Indication under review: for the treatment of hyperkalaemia in adults.
Restriction: chronic use [maintenance phase] for adults with persistent/recurrent hyperkalaemia and heart failure, with or without chronic kidney disease stage 3b to 5 if they:
- **have a confirmed serum potassium level of at least 6.0mmol/litre and**

ITEM	SUBJECT	ACTION

- **are not taking an optimised dosage of renin-angiotensin-aldosterone system (RAAS) inhibitor because of hyperkalaemia**
- **stop sodium zirconium cyclosilicate if RAAS inhibitors are no longer suitable**

It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment must be initiated and supervised by specialist physicians in the Heart Failure/Cardiology department. **FTEAM**

5. NEW PRODUCT REQUESTS

5.2. SMC 2650 - MIRIKIZUMAB (MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS)

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

The Group considered the request for mirikizumab for the treatment of adults 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 treatment.

The Group noted that:

- mirikizumab:
  - [for this indication] was accepted for use in NHS Scotland following an abbreviated submission reviewed by the SMC executive
  - is a humanised IgG4 monoclonal, anti-interleukin-23 (anti-IL-23) antibody that blocks the activity of IL-23, a protein that controls the growth and maturation of some types of T cells. These T cells are part of the immune system involved in causing inflammation that is linked to the development of ulcerative colitis. By blocking the action of IL-23, mirikizumab reduces inflammation and symptoms associated with the disease.
  - is administered as a loading dose, 300mg by intravenous infusion at weeks 0, 4 and 8, but may be continued at weeks 12, 16 and 20 (extended induction therapy). Patients should be evaluated after the 12-week induction dosing, and mirikizumab should be discontinued in patients who do not show evidence of therapeutic benefit to extended induction therapy by week 24.
  - maintenance dosing is continued at 200mg by subcutaneous injection every 4 weeks after completion of induction dosing.
- efficacy and safety data for mirikizumab versus placebo are derived from two randomised, double-blind, placebo-controlled phase III studies (LUCENT-1 and LUCENT-2) in patients with moderately to severely active ulcerative colitis who had an inadequate response to, loss of response to, or were intolerant to conventional or biologic therapy for UC
- LUCENT-1 and LUCENT-2:
  - the primary endpoint for both studies was the proportion of subjects in clinical remission
  - after 12 weeks, mirikizumab induced clinical remission in a greater proportion of patients compared with placebo in LUCENT-1
  - patients who achieved clinical remission in LUCENT-1 could enter the maintenance study (LUCENT-2). Clinical remission at 40 weeks was achieved in a greater proportion of patients in the mirikizumab group compared with placebo.
  - patients in these studies may have received other concomitant therapies including aminosalicylates (74.3%), immunomodulatory agents (24.1% such as azathioprine, 6-mercaptopurine or methotrexate), and oral corticosteroids (39.9%; prednisone daily dose up to 20mg or equivalent) at a stable dose prior to and during the induction period. Per protocol oral corticosteroids were tapered after induction.
- limitations of the data:
  - the lack of direct evidence against active comparators
  - short term data [52 weeks; 40 weeks maintenance], with limited efficacy and safety data in the maintenance setting for a potentially long term treatment

  - insufficient data to know if there will be a treatment waning effect
  - studies included biologic-naïve patients which is not a relevant population for the local treatment pathway
- ustekinumab is another interleukin inhibitor that is included on the formulary and licensed for moderately to severely active ulcerative colitis for adults 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.
- biosimilar ustekinumab is expected this year, with the first biosimilar expected from July
- the service has stated that mirikizumab will be used as a last-line agent after other agents have been considered/used
- costs will be cumulative as treatment is potentially lifelong, and cost offset will be available from displacement of other therapies
- there are no patients waiting for treatment
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of mirikizumab

The Group accepted the restricted local need for mirikizumab as an additional, potentially last-line, treatment option for adults with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to biologic treatment.

SMC 2650 - Mirikizumab 100mg, 300mg solution for injection in pre-filled pen and concentrate for solution for infusion (Omvoh®)▼ is routinely available in line with local guidance.
Indication under review: for the treatment of adults 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 treatment.
Restriction: for adults who have had an inadequate response with, lost response to, or were intolerant to biologic treatment.
Mirikizumab offers an additional treatment choice in the therapeutic class of interleukin inhibitors.
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.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
This medicinal product is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of ulcerative colitis. **FTEAM**

5.3. FG1 450/22 – XONVEA® (SEVERE NAUSEA AND VOMITING IN PREGNANCY)

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

The Group considered the request for Xonvea® for the treatment of severe nausea and vomiting in pregnancy (NVP) and Hyperemesis Gravidarum (HG).

The Group noted that:
- Xonvea®:
  - is a slow-release fixed-dose combination product, containing doxylamine succinate (antihistamine) and pyridoxine hydrochloride (vitamin B6), that provides anti-nauseant and antiemetic activity
  - is an oral tablet and the recommended starting dose is two tablets at night. Depending on symptom control the dose can be increased to three or four tablets daily (addition of one tablet in the morning, and then one at lunch).
  - is the only treatment licensed for the management of nausea and vomiting in pregnancy. It is licensed *for the treatment of nausea and vomiting of pregnancy*

(NVP) in pregnant women ≥18 years who do not respond to conservative management (i.e., lifestyle and diet change)
  - was not recommended by SMC for use in NHS Scotland following a full submission (SMC 2140, May 2019)
  - is recommended as an additional first-line choice in the latest update of the Royal College of Obstetricians and Gynaecologists, 2024 Guideline The Management of Nausea and Vomiting in Pregnancy and Hyperemesis Gravidarum (Green-top Guideline No.69, published February 2024)
- Green-top Guideline No.69:
  - provides a review of the evidence (efficacy, safety and adverse effects) for the pharmacological treatment options, including a suggested step wise approach to treatment
  - lists a key recommendation (Grade A evidence) that there are safety and efficacy data for first-line antiemetics such as anti (H1) histamines, phenothiazines and doxylamine/pyridoxine (Xonvea®) and they should be prescribed initially when required for NVP and HG
- [February 2024] NICE Clinical Knowledge Summaries (CKS) Nausea/vomiting in pregnancy was updated, and includes Xonvea® as a first-line option, in line with Green-top Guideline No.69
- NVP affects up to 90% of pregnant women and is one of the most common indications for hospital admission among pregnant women, with typical stays of between three and four days
- Xonvea® is more expensive [£85.50 to £171 for 30 days] than the alternative first-line antihistamines tablets, however it costs significantly less than a hospital admission
- the symptoms of NVP and HG can have a profound and debilitating effect on women and their families, with some women considering termination of a wanted pregnancy
- it is important to consider the effects to the mother and baby from unmanaged dehydration and malnutrition

A member requested a minor change to the draft guidance, and members were given until 29 August to feedback comments on the draft local NVP and HG guidance. **ALL**

The Group noted that Xonvea® is the first medicine licensed for NVP, and accepted the restricted local need for Xonvea® for the treatment of pregnant women with severe NVP and HG.

FG1 450/22 – Xonvea® 10mg/10mg gastro-resistant tablets (doxylamine succinate/pyridoxine hydrochloride) is routinely available in line with local guidance.
Indication under review: for the treatment of severe nausea and vomiting of pregnancy (NVP) and Hyperemesis Gravidarum (HG).
It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care. **FTEAM**

5.4. FG1 467/24 - DARATUMUMAB IN COMBINATION WITH BORTEZOMIB, LENALIDOMIDE AND DEXAMETHASONE (OFF-LABEL USE FOR NEWLY DIAGNOSED MULTIPLE MYELOMA)

There were no declarations of interest recorded in relation to generic lenalidomide.

The Group considered the request for the off-label use of a four-drug regimen, daratumumab in combination with bortezomib, lenalidomide and dexamethasone (Dara-VRD), for the treatment of adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. The suggested change is to exchange thalidomide with lenalidomide in the SMC approved Dara-VTD induction regimen.

The Group noted that:
- Dara-VRD for adults with newly diagnosed multiple myeloma who are eligible for

ITEM	SUBJECT	ACTION

autologous stem cell transplant is considered outwith NCMAG remit, so proposals need to considered by individual Health Boards
- lenalidomide:
  - is now off-patent, and it is unlikely that a pharmaceutical company will apply for a licence for Dara-VRD induction
  - is more effective and less toxic than thalidomide (particularly for peripheral neuropathy)
- there are no head-to-head data comparing Dara-VTD with Dara-VRD
- there are data comparing VTD with VRD in transplant eligible myeloma, which showed VRD was superior for response with less treatment emergent adverse events leading to study and/or treatment discontinuation
- the addition of daratumumab either to VRD or VTD improves the outcomes for newly diagnosed transplant-eligible myeloma patients. Dara-VRD [compared with Dara-VTD] led to more patients with a VGPR (Very Good Partial Response) and higher MRD (Minimal Residual Disease) negative rate.

Dr Culligan confirmed that overall the side-effect profile and efficacy of VRD is better than VTD, and there is unanimous agreement amongst haematologists [that treat myeloma] that Dara-VRD is the preferred regimen for newly diagnosed multiple myeloma patients who are eligible for autologous stem cell transplant.

The Group accepted the restricted local need for the off-label use of Dara-VRD for the treatment of adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.

FG1 467/24 - Daratumumab 1800mg solution for injection, 20mg/mL concentrate for solution for infusion (Darzalex®) is routinely available in line with local guidance.
Indication under review: [off-label] in combination with bortezomib, lenalidomide and dexamethasone for the treatment of adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.
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 3b - licensed product requested for unlicensed use and 8b - recommended for hospital use only. . **FTEAM**

6. FORMULARY REVIEW

6.1. SBAR - CAR-T THERAPY AND RELATED MEDICINES

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

The Group considered the SBAR requesting formulary inclusion of the CAR-T (chimeric antigen receptor T-cell) therapies manufactured by Gilead, and the immunosuppressant interleukin inhibitors required to manage CAR-T associated cytokine release syndrome (CRS) or Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS).

Dr Culligan confirmed that over the past few years a lot of effort has gone into gaining JACIE* accreditation, and working with the Scottish Government, to authorise NHS Grampian to deliver these a highly complex and innovative treatments.
Going forward CAR-T therapies will be a major item for haematology and likely so for oncology in the future.

JACIE is a quality management system, the whole process is very protocol driven, and patients will not receive CAR-T therapy unless the national MDT has approved the

* The Joint Accreditation Committee ISCT-Europe & EBMT (JACIE)

ITEM	SUBJECT	ACTION

patient.

Mrs Howlett outlined the work that has been undertaken so far, including the extensive documentation required and the on-boarding process with Gilead.

Mrs Howlett confirmed that:
- there is not a defined starting date, but potentially October
- extended provision (staffing) and funding is in place
- the supporting medicines must be available for emergency use on the ward
- the service will treat adults (18 years and older)
- the on-boarding process for the Novartis product will start later this year

Members accepted that the three supportive medicines must be ready for use on the ward.

The Group supported the request to reclassify the CAR-T therapies manufactured by Kite Gilead from non-formulary to formulary, and include the immunosuppressant interleukin inhibitors on the formulary to manage CAR-T associated CRS or ICANS, including the off-label use of anakinra and siltuximab.

SBAR - Brexucabtagene autoleucel 0.4 - 2 × 10^8 cells dispersion for infusion (Tecartus®)▼:
- **is routinely available in line with national guidance, on an interim basis subject to ongoing evaluation and future reassessment (SMC 2351).**
  Indication under review: for the treatment of adults with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor.
- **is routinely available in line with national guidance (SMC 2548).**
  Indication under review: for the treatment of adults 26 years of age and above with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL).

It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Tecartus® must be administered in a qualified treatment centre by a physician with experience in the treatment of haematological malignancies and trained for administration and management of patients treated with Tecartus®. **FTEAM**

SBAR - Axicabtagene ciloleucel 0.4 - 2 × 10^8 cells dispersion for infusion (Yescarta®)▼ is routinely available in line with national guidance (SMC 2189).
Indication under review: for the treatment of adults with relapsed or refractory diffuse large B cell lymphoma (DLBCL) and primary mediastinal large B cell lymphoma (PMBCL), after two or more lines of systemic therapy.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Yescarta® is intended for autologous use only. Yescarta® must be administered in a qualified treatment centre by a physician with experience in the treatment of haematological malignancies and trained for administration and management of patients treated with Yescarta®. **FTEAM**

SBAR - Tocilizumab 20mg/mL concentrate for solution for infusion (Tyenne®)▼ is routinely available in line with local guidance.
Indication: for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of CRS. **FTEAM**

ITEM	SUBJECT	ACTION
	SBAR - Anakinra 100mg/0.67mL solution for injection in pre-filled syringe (Kineret®) is routinely available in line with local guidance. **Indications under review:** **a) [off-label] for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening grade 4 cytokine release syndrome (CRS) in adults with no improvement after dexamethasone.** **b) [off-label] for the treatment of grade 3 or 4 Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS) where steroid response is suboptimal or ICANS worsens on tapering of steroids.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.** **Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of CRS or ICANS.**	**FTEAM**
	Siltuximab 100mg, 400mg powder for concentrate for solution for infusion (Sylvant®)▼ is routinely available in line with local guidance. **a) [off-label] for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening grade 4 cytokine release syndrome (CRS) in adults in refractory cases.** **b) [off-label] for the treatment of persistent grade 3 or 4 Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS) despite high dose steroids and anakinra.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.** **Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of CRS or ICANS.**	**FTEAM**

6.2. FSRH CEU STATEMENT: EXTENDED USE OF ALL 52MG LNG-IUDS FOR UP TO EIGHT YEARS FOR CONTRACEPTION

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

The Group considered the Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit (FSRH CEU) statement supporting the extended use of all 52mg levonorgestrel intrauterine device (LNG-IUDs) for up to eight years for contraception.

The Group noted that:

- the current formulary 52mg LNG-IUDs, Mirena® and Levosert®, are now both licensed for contraception for up to 8 years
- Benilexa® One Handed is not included on the formulary, and is currently the only 52mg LNG-IUD not licensed for up to eight years for contraception
- it may be useful to include Benilexa® One Handed on the formulary, especially from a North of Scotland Patient Group Direction (PGD) perspective

The Group accepted the FSRH position supporting the extended use of any 52mg LNG-IUD for up to eight years for contraception, including the off-label use of Benilexa® One Handed.

	Levonorgestrel 52mg (20micrograms/24 hours) Intrauterine Delivery System (Mirena®, Levosert®) is routinely available in line with local guidance. **Indications under review: for contraception (licence extension up to 8 years).** **It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.**	**FTEAM**
	Levonorgestrel 52mg (20micrograms/24 hours) Intrauterine Delivery System (Benilexa® One Handed) is routinely available in line with local guidance. **Indications under review: contraception (as licensed up to 6 years).**	

ITEM	SUBJECT	ACTION
	It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.	**FTEAM**
	Levonorgestrel 52mg (20micrograms/24 hours) Intrauterine Delivery System (Benilexa® One Handed) is routinely available in line with national guidance (FSRH). **Indications under review: [off-label] as contraception:** • **for up to 8 years if the user is under 45 years at time of insertion** • **until the age of 55 years if the user is over the age of 45 years at the time of insertion** **It was classified 3b - licensed product requested for unlicensed use and 8e - treatment may be initiated in either Primary or Secondary care.**	**FTEAM**

7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED JULY 2024

The Group noted the SMC advice published July 2024.

Following publication of the negative SMC recommendation, for pembrolizumab (Keytruda®) SMC 2644, and the non-submission statements, for lenacapavir (Sunlenca®)▼ SMC 2691, remimazolam (Byfavo®)▼ SMC 2692 and trastuzumab deruxtecan (Enhertu®)▼ SMC 2693, these medicines will not be included on the Grampian Joint Formulary for the indications in question.

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

- SMC 2642 empagliflozin (Jardiance®)
- SMC 2670 follitropin delta (Rekovelle®)
- SMC 2713 Kaftrio®▼ (elexacaftor/ivacaftor/tezacaftor)
- SMC 2645 Opdualag®▼ (nivolumab/relatlimab)
- SMC 2712 Orkambi® (lumacaftor/ ivacaftor)
- SMC 2665 pegunigalsidase alfa (Elfabrio®)▼
- SMC 2660 pembrolizumab (Keytruda®) (submission received)
- SMC 2711 Symkevi® (tezacaftor/ivacaftor)

Local advice for these medicines and indications will be included in the August 2024 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

SMC 2641 - VORETIGENE NEPARVOVEC (LUXTURNA®)▼

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

The Clinical Lead for Ophthalmology confirmed that there is not a local need for this medicine at this time. Previously it was agreed that treatment should be provided from a more central location to cover whole of Scotland.

This medicine will not be included on the Grampian Joint Formulary for this indication.

SMC 2641 - Voretigene neparvovec 5 x 10^{12} vector genomes/mL concentrate and solvent for solution for injection (Luxturna®)▼ is routinely available from a specialist centre in another health board.
Indication under review: for the treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations and who have sufficient viable retinal cells.
In a phase III open-label study of patients with vision loss due to inherited retinal

ITEM	SUBJECT	ACTION

dystrophy due to RPE65 mutations, functional vision was significantly improved from baseline to one year in the voretigene neparvovec group compared with the control group.
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 the views from a Patient and Clinician Engagement (PACE) meeting.
Not routinely available in NHS Grampian. If local need identified treatment is available from a specialist centre in another health board.
Treatment should be initiated and administered by a retinal surgeon experienced in performing macular surgery. **FTEAM**

7.2. UMAR PUBLISHED JULY 2024

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

In line with local processes, and pending confirmation that this medicine is available for prescribing within the ultra-orphan pathway, the Formulary Group recorded birch bark extract gel as 'not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI).'

UMAR SMC 2651 - Birch bark extract gel (Filsuvez®) is not routinely available in NHS Grampian.
Indication under review: for the treatment of partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients 6 months and older.
Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI). **FTEAM**

7.3. NCMAG ADVICE PUBLISHED JULY 2024

The Group noted the NCMAG advice published July 2024

The following NCMAG supported medicine and indications have not been processed within a 60-day timescale:
- NCMAG 116 dasatinib (submission expected)
- NCMAG 117 dasatinib

Local advice for this medicine and indications will be included in the August 2024 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

7.4. SMC ADVICE PUBLISHED – AUGUST 2024

The Group noted the SMC advice published August 2024.

Following publication of the non-submission statements, for fezolinetant (Veoza®)▼ SMC 2702, nivolumab (Opdivo®) SMC 2704, talquetamab (Talvey®)▼ SMC 2705 and trastuzumab deruxtecan (Enhertu®)▼ SMC 2706 these medicines will not be included on the Grampian Joint Formulary for the indications in question.

The following SMC accepted medicine has not been processed within a 60-day timescale:
- SMC 2654 Lonsurf® (trifluridine/tipiracil) (submission expected)

Local advice for this medicine and indication will be included in the August 2024 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

ITEM	SUBJECT	ACTION

SMC 2649 - ETRANACOGENE DEZAPARVOVEC (HEMGENIX®)▼

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

The Haematology Service confirmed that there is not a local need for this medicine at this time. Currently there are discussions amongst Scottish Haemophilia Centre directors as to whether it is best that one centre in Scotland delivers the treatment.

This medicine will not be included on the formulary for this indication.

SMC 2649 - Etranacogene dezaparvovec 1 x 10^{13} genome copies/mL concentrate for solution for infusion (Hemgenix®)▼ is routinely available from a specialist centre in another health board.
Indication under review: for the treatment of severe and moderately severe haemophilia B (congenital factor IX deficiency) in adult patients without a history of factor IX inhibitors.
In an open-label, non-randomised, single-arm, phase III study, the annualised bleeding rate was reduced following treatment with etranacogene dezaparvovec compared with a lead-in period of regular factor IX prophylaxis.
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 the views from a Patient and Clinician Engagement (PACE) meeting.
Not routinely available in NHS Grampian. If local need identified treatment is available from a specialist centre in another health board.
Treatment should be initiated under the supervision of a physician experienced in the treatment of Haemophilia and/or bleeding disorders. This medicinal product should be administered in a setting where personnel and equipment are immediately available to treat infusion related reactions. **FTEAM**

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED AUGUST 2024

The Group noted the SMC provisional advice issued August 2024.

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

9. OTHER BUSINESS

9.1. NCMAG QUARTERLY UPDATE JULY 2024 (FOR INFORMATION)

Members noted NCMAG quarterly update.

10. DOCUMENTS FOR INFORMATION

Items 10.1 (Drug Safety Update June 2024), 10.2 (Drug Safety Update July 2024), 10.3 (MedWatch June 2024), 10.4 (Antimicrobial Management Team minute May 2024), 10.5 (Antimicrobial Management Team minute June 2024), 10.6 (Grampian Primary Care Prescribing Group meeting minute May 2024) and 10.7 (Acute and Mental Health Medicines Safety Group meeting minute May 2024) were noted.

ITEM	SUBJECT	ACTION

11. AOCB

TOPIRAMATE - INTRODUCTION OF NEW SAFETY MEASURES

Ms Davie requested an update on the local situation regarding topiramate and the new safety measures introduced in June.
An update will be provided at the September meeting. **FTEAM**

BMS STATEMENT ON TESTOSTERONE

Ms Doney reported that the British Menopause Society issued a potentially useful statement on the pressure to prescribe testosterone for women.
The link to the statement will be included on the formulary newsfeed, and send via email to members for information. **FD**

DATE OF NEXT MEETING

Tuesday 17 September 2024 starting at 14.30 via Microsoft Teams

Dr Louise Elliot

CHAIR'S SIGNATURE **Signature on file** **DATE 17 SEPTEMBER 2024**