NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 17 May 2022 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms L Cameron	Dr D Culligan	
Ms A Davie	Mr R Sivewright	
Ms F Doney (Vice-Chair)		
Dr L Elliot (Chair)		
Ms M Galvin		
Mrs G McKerron		
Dr M Metcalfe (Vice-Chair)		
Mrs L Montgomery		
Mrs K Neave		
Dr J Newmark		
Mrs S O'Beirne		
Mr M Paterson		

IN ATTENDANCE
Dr Michelle McNeil, Consultant Dermatologist and Clinical Lead, for item 3.1
Dr Shirley English, Associate Specialist, for item 3.2
Dr Vui Yung Chieng, GP at Links Medical Practice, observer
Mrs Anne Rembisz, Formulary Team administrator

Note some items were taken outwith the agenda running order.

ITEM	SUBJECT	ACTION

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

The Chair welcomed Dr Vui Chieng, an Aberdeen City GP, to the meeting as an observer with a view to joining the Formulary Group.

1. APOLOGIES

Apologies for absence were requested and noted.

3. PRESENTATION

3.1. DR MCNEIL - DAPSONE

The Chair welcomed Dr Michelle McNeil, Consultant Dermatologist, to the meeting to discuss the Group's decision regarding the use of dapsone in dermatological conditions.

Dr McNeil provided an overview of the departments concerns regarding the recent formulary classification of dapsone.

Dr McNeil reported that:
- the request for formulary inclusion of dapsone was with the intent of establishing a shared care arrangement to give colleagues in Primary Care robust and consistent monitoring guidance, and support to prescribe dapsone
- the department feels that a shared care arrangement will have a positive impact on patient safety [with regards to dapsone prescribing]
- there are shared care arrangements implemented in some other Health Boards, but there is a mix of prescribing from the managed service and Primary Care
- the Dermatology Service does not prescribe dapsone, all prescribing is via Primary Care under the recommendation of dermatology, so moving to hospital prescribing will be a deviation from current practice

ITEM	SUBJECT	ACTION

- dapsone:
  - is often used off-label, there is not an extensive evidence base for its use in these conditions, or licensed alternatives for these conditions
  - if effective, is a long-term treatment
  - provides benefits over newer therapies (particularly for the elderly, those with comorbidities or history of malignancy) as it is not immunosuppressive
- the Service:
  - does not have the infrastructure to safely initiate and manage the number of patients on dapsone
  - feels that attending community hubs for both phlebotomy and prescription collection may be limiting for patients, particularly initially when the monitoring frequency is at its highest
  - feels that the patients that would benefit most [from dapsone] would be those that have the most difficulty travelling the greatest distance to collect their prescription and attend for monitoring
- because of the concerns regarding the lack of infrastructure to safely manage patients the service may consider moving to biologics that potentially have a higher side-effect burden

Members clarified the reasons behind the Group's decision and Dr McNeil responded to queries from members.

There was agreement that dapsone requires quite intensive blood monitoring, particularly at the start of therapy. A shared care arrangement clarifies the clinical information/responsibilities, however, the financial burden to Primary Care is another consideration and this is a matter for other groups.
There was a general understanding that individuals are responsible for what they prescribe, and this becomes more difficult when the request is for specialist drugs that are rarely used across a wide range of indications, many of which are unlicensed.

Ms Davie stated that changes to the GP contract mean that patients may be going to Secondary Care blood hubs/community treatment and advice centres for their blood monitoring not their General Practice.

The Chair thanked Dr McNeil for attending the meeting, and Dr McNeil left the meeting before decision-making.

4.3. DAPSONE

The Group discussed the points raised by Dr McNeil on behalf of the Dermatology Service.

The Group noted:
- prescribing data shows that there is a cohort of patients receiving dapsone via Primary Care
- the number of indications included in the request, and that the majority are off-label indications. Primary Care colleagues do not have the specialist knowledge of each of these conditions, and the small patient numbers spread across multiple indications provides an additional challenge to gaining experience.
- it would be appropriate for prescribing to remain with the specialists that understand the drug and its monitoring needs
- for patients currently receiving dapsone in Primary Care where a clinician-to-clinician discussion has already taken place prescribing will remain unchanged, new starts should be prescribed and monitored by Secondary Care
- clinicians have the option to request use on an individual patient basis

The Group upheld its previous decision accepting dapsone for its licensed indication, and hospital prescribing for new patients. This position does not affect patients already established on treatment. **FTEAM**

ITEM	SUBJECT	ACTION

2. DRAFT MINUTE OF THE MEETING HELD 19 APRIL 2022

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**

4. MATTERS ARISING

4.1. ACTION LOG

The action log was noted.
No additional items were identified that should have been included on the agenda. **FTEAM**

4.2. STATIN INTOLERANCE PATHWAY

Ms Doney confirmed that the request for guidance to help colleagues assess 'true' statin intolerance is related to the availability of new lipid-lowering therapies that cost significantly more than statins, but that at present, do not have data showing a reduction in cardiovascular events.
Colleagues are adapting the NHS England statin intolerance pathway and, when finalised, it will be hosted on Grampian Guidance.

A 'once-for-Scotland' adaption of the guidance will not be available from Healthcare Improvement Scotland (HIS) or Scottish Intercollegiate Guidelines Network (SIGN).

The draft guidance will be shared with members. **FTEAM**

Members agreed that from time-to-time it would be prudent to monitor the evidence for the newer lipid-lowering agents, not only looking for mortality data but also to confirm these agents are doing no harm. **FTEAM**

3. PRESENTATION

3.2. PRESENTATION DR ENGLISH (LOLA SACHETS)

The Chair welcomed Dr Shirley English, Associate Specialist, to the meeting to discuss the submission for L-Ornithine-L-Aspartate (LOLA) sachets for the treatment of hepatic encephalopathy (HE).

Dr English provided the Group with an overview of HE and its management, before discussing the formulary request for LOLA.

Dr English reported that:
- LOLA is an agent that the service has been using for HE
- HE:
  - is a significant problem in cirrhotic patients
  - is a potentially reversible function disorder of the brain with neurological and psychiatric symptoms that is caused by a build-up of ammonia in the body. Ammonia crosses the blood-brain barrier causing a range of symptoms from movement disorders, mild confusion, through to coma Grade 4.
  - has a significant cost to the patient (quality of life, care needs) and the Board (in-patient and out-patient cost)
- the mainstay of HE treatment is preventing the production of ammonia by sterilising the bowel with antibiotics (rifaximin) and using laxatives (lactulose) to reduce bowel contents

LOLA:
- promotes the excretion/processing of ammonia
- is used in advanced liver disease so patients have a relatively poor prognosis
- can be part of end-of-life care in late stage liver disease for difficult to control encephalopathy
- is used to improve the patient's quality of life, to try and maintain out-patient care and reduce hospital admissions
- is also used in difficult to manage HE while patients are awaiting transplant
- is an add-on treatment usually started in hospital following admission of patients that are not responding to standard treatments (lactulose plus rifaximin)

- evidence for LOLA is lacking
- anecdotal data/local case studies showed less confusion, less care requirements and reduced hospital admissions for a small cohort of patients
- the Service wishes to include LOLA on the formulary because:
  - it is becoming an increasingly recognised treatment for HE
  - it is recommended by the Transplant Centre in Edinburgh, so sometimes the local specialists are prescribing based on the Transplant Centre's recommendation
  - there is a concern that this is a vulnerable group. Often these patients are confused and on occasions have forgotten to pick up their medication from the hubs, so there is a desire to make it easier for patients to obtain their LOLA prescriptions. It would be easier for patients if prescribing and dispensing was from one place along with their other medicines, with the added benefit of clearer documentation at medicines reconciliation.

Dr English responded to queries from members and confirmed that:
- patients are given a 3-month trial, reviewed at least twice in that period, and treatment is only continued if LOLA is effective (confusion and ammonia levels have decreased)
- treatment is usually started when the patient is an in-patient
- the dose is one sachet three times a day
- patients are closely monitored after discharge by the Close Monitoring Clinic - run by liver specialist nurses, with support from specialists
- follow-up is a combination of face-to-face and telephone appointments
- there is no specific blood monitoring for LOLA, but patients have routine bloods as part of their liver follow-up

The Chair thanked Dr English for attending the meeting, and Dr English left the meeting before decision-making.

8.1. FG1 445/21 - LOLA SACHETS (UNLICENSED PRODUCT – HEPATIC ENCEPHALOPATHY)

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

The Group considered the request for LOLA sachets for the treatment of adults with HE, unresponsive to lactulose +/- rifaximin and for patients with HE awaiting liver transplant.

The Group noted:
- HE is debilitating and associated with a greater risk of death than other significant hepatic decompensation events
- LOLA
  - is requested as a last-line add-on treatment for patients with recurrent HE or until the patient receives a liver transplant
  - stimulates ammonia detoxification by increasing synthesis of urea in the liver and glutamate in the skeletal muscle
  - has a different mode and site of action to the standard treatments
  - treatment is reviewed after three months, if confusion and ammonia levels have decreased the treatment would be continued

  - evidence for use is poor, but it is noted in some guidance – British Medical Journal Best Practice - Hepatic encephalopathy in patients with cirrhosis (2020), and Joint American (AASLD) and European (EASL) guideline Hepatic Encephalopathy in Chronic Liver Disease: 2014 Practice Guideline
  - is used in other Scottish Health Boards but is not included on formularies
  - is included on a few English formularies but is available for hospital prescribing only
  - is recommended by the Edinburgh Liver Transplant Unit for patients who are awaiting transplant, including recommendations for GPs to prescribe treatment
- the average wait for a liver transplant in the UK is 3 to 4 months
- patient numbers are expected to be small, and treatment is unlikely to be long-term
- treatment represents an additional cost as LOLA is an adjunctive treatment
- the service requested prescribing in Primary Care on the advice of a specialist

The following points were noted:

- *Clinical effectiveness:* evidence is poor, mainly case reports/meta-analysis of case reports. The double blind studies have not been reported, so there is no evidence one way or the other. For responders, there is the potential for increased quality of life and reduction in hospital admission for HE.
- *Cost effectiveness:* no QALY data, but not a significantly expensive product, potentially given short-term (particularly when used pre-transplant), with the potential to maintain patients in out-patient care and reduced hospital admissions (in responders)
- *Health gain for NHSG:* based on local estimates seven to ten patients per annum would receive treatment. As a possible last line adjunctive therapy, LOLA may provide the opportunity for improved quality of life (for patients and carers/family)
- *Service impact:* no service developments are required to provide treatment. The service impact is expected to be low because of the small patient numbers and relatively low treatment costs.
- *Equity:* the overall cost of treatment is moderate and other medicines are not expected to come to market for this indication in the near future. LOLA is used in other areas in NHS Scotland (and NHS England), but is not noted in any NHS Scotland formularies. LOLA is recommended by the Liver Transplant Unit so could put the service in a difficult position if LOLA is not included on the formulary.
- *Safety:* no new or specific issues noted

Members acknowledged that recurrent HE has a significant impact on a patient's quality of life and that the quality of the evidence for LOLA was low, but in responders it has the potential for a beneficial effect on mortality.

Taking account of the poor prognosis of this patient group, that LOLA is a last-line/end-of-care option and that the Transplant Service recommends treatment for patients awaiting transplant, the Group accepted the restricted local need for the unlicensed product LOLA for the treatment of a small group of adults with HE. Prescribing and supply will remain in the managed service.

FG1 445/21 - L-Ornithine-L-Aspartate (LOLA) 3g granules for oral solution is routinely available in line with local guidance.
Indication under review: [unlicensed product] for the reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients ≥18 years of age.
Restriction: as add-on treatment for adults with recurrent HE:

- **who cannot be adequately controlled with standard therapy alone (lactulose +/- rifaximin)**
- **who are awaiting liver transplant**

It was classified 3a - unlicensed product [available for restricted use under specialist supervision] and 8b - recommended for hospital use only. Informed consent should be obtained and documented. **FTEAM**

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Members noted that both presenters highlighted that the collection hubs are not necessarily good for their patients. These comments should be reported to the Grampian Area Drug and Therapeutics Committee (GADTC) to ensure this is noted and addressed. **FTEAM**

RIFAXIMIN 550MG FILM-COATED TABLETS (TARGAXAN®)

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

The Group discussed the proposal to update the current formulary entry for rifaximin 550mg tablets (Targaxan®).

The Group noted:

- rifaximin 550mg as Targaxan®:
  - is currently included on the formulary – '*for the reduction in recurrence of episodes of overt HE in adults. Restricted to use as a second-line antibiotic in adults who present with recurrent encephalopathy despite being on lactulose and neomycin'*
  - is an 'Alert' antimicrobial that should only be prescribed in Primary Care for HE on the advice of a GI specialist
- neomycin use in HE has reduced, it is no longer used locally, and the UK licensed product was discontinued last year
- lactulose remains the first-choice agent (alternative laxatives may be tried in patients intolerant of lactulose)
- rifaximin is a second-line treatment, used in combination with lactulose for recurrent episodes of overt HE

The Group accepted that the current formulary entry for Targaxan® does not reflect current usage and supported updating the formulary in line with current practice.

Rifaximin 550mg film-coated tablets (Targaxan®) is routinely available in line with local guidance.
Indication under review: for the reduction in recurrence of episodes of overt hepatic encephalopathy in patients ≥18 years of age.
Restriction: second-line in adults who present with recurrent encephalopathy despite being on lactulose/laxatives.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.
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**

4. 4.3. CORTIMENT® TAPERING

Ms Doney reported that the Gastroenterology Service does not taper the Cortiment® dose at the end of treatment. Item closed.

4.4. MICRONISED PROGESTERONE (THREATENED MISCARRIAGE)

Ms Doney stated that the Service has confirmed that Cyclogest® 400mg pessaries would be the first-choice agent, with Cyclogest® 200mg pessaries available if there are supply issues with the 400mg pessaries.
Utrogestan Vaginal® would be used as a second-line option for patients who have had previous adverse reactions to Cyclogest®, where they wish to try another preparation in a subsequent pregnancy where Cyclogest® did not work, or where they specifically request Utrogestan Vaginal®.

The Group supported the Service's request for micronised progesterone 200mg pessaries (Cyclogest®) and 200mg vaginal capsules (Utrogestan Vaginal®) as second-line

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options for the management of threatened miscarriage in women with vaginal bleeding who have a confirmed pregnancy, with a history of one or more previous miscarriages, as per NG126.

FG1 446/22 - Micronised progesterone 200mg pessaries (Cyclogest®) is routinely available in line with local guidance.
Indication under review: [off-label use] management of threatened miscarriage in women with vaginal bleeding who have a confirmed pregnancy and with a history of one or more previous miscarriages.
Restriction: second-line option in line with local guideline 'Management of threatened miscarriage (including the use of progesterone where applicable)'.
It was classified 3b - licensed product requested for off-label use [available for restricted use under specialist supervision] and 8b - recommended for hospital use only. Informed consent should be obtained and documented. **FTeam**

FG1 447/22 - Micronised progesterone 200mg vaginal capsules (Utrogestan Vaginal®) is routinely available in line with local guidance.
Indication under review: [off-label use] management of threatened miscarriage in women with vaginal bleeding who have a confirmed pregnancy and with a history of one or more previous miscarriages.
Restriction: second-line option in line with local guideline 'Management of threatened miscarriage (including the use of progesterone where applicable)'.
It was classified 3b - licensed product requested for off-label use [available for restricted use under specialist supervision] and 8b - recommended for hospital use only. Informed consent should be obtained and documented. **FTeam**

5. FORMULARY GROUP DECISIONS APRIL 2022 - PUBLISHED 02/05/2022

Members ratified the decisions of the April 2022 meeting as published. **FTEAM**

6. NETFORMULARY/FORMULARY REVIEW

6.1. ISAVUCONAZOLE 100MG CAPSULES (RECLASSIFICATION)

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

Ms Doney reported that:
- isavuconazole, as 100mg capsules, is now only available in a ‘hospital-only’ pack
- previously it was available for prescribing in Primary Care and its formulary classification was 1b- available for restricted use under specialist supervision and 8c - treatment to be initiated in hospital prior to handover
- the formulary classification needs to be updated to reflect the change to a ‘hospital-only’ pack
- the formulary website has already been updated

The Group ratified the reclassification of isavuconazole 100mg capsules from ‘8c’ to ‘8b - recommended for hospital use only’. **FTEAM**

6.2. ESKETAMINE (SPRAVATO®)

Ms Doney reported that because Spravato®/esketamine may be subject to abuse and diversion, from 1 April 2022, all patients must be enrolled to the ‘Spravato Register And Alert System’.
This information has been shared with the Mental Health Service to take forward, including consideration of any information governance issues related to the register. The information has been linked to the relevant formulary entry. **FTEAM**

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7. OTHER BUSINESS

7.1. UPDATE TO SUBMISSION FORMS TO ADD 'HOSPITAL-ONLY' PACK DESIGNATION

Ms Doney reported that the Formulary Team reviews will now highlight products that are available as hospital-only packs. The submission forms have been updated and will filter into use in the next few months.

7.2. DRAFT HIS STRATEGY

Ms Doney confirmed that comments on the draft Healthcare Improvement Scotland (HIS) Strategy should be emailed to HIS directly, details will be emailed to members after the meeting. **FTEAM**

8. NEW PRODUCT REQUESTS

Items 8.2 and 8.3 were taken together.

8.2. FG1SMC 2398 - TUCATINIB (BREAST CANCER)

8.3. FG1SMC 2388 - TRASTUZUMAB DERUXTECAN (BREAST CANCER)

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

The Group considered the requests for tucatinib [in combination with trastuzumab and capecitabine] and trastuzumab deruxtecan monotherapy for the treatment of adults with HER2-positive locally advanced or metastatic breast cancer who have received at least two prior anti-HER2-based regimens.

Members noted that, looking at the drug cost alone, using the tucatinib regimen, intravenous trastuzumab offers a cost avoidance per patient compared to subcutaneous trastuzumab.
Members discussed the use of the different regimens in the same patient population, noting that there is no head-to-head data, or evidence for sequencing treatments but the regimens would be offered fourth-line/as alternative lines of therapy if patients progress on one.

Ms Galvin confirmed that these agents would be offered as alternative lines of treatment if patients progressed on one, and this would be standard practice across the breast cancer treatment pathways throughout Scotland. There is a move to develop national clinical management guidelines. This work is still in development and breast is one of the tumour groups being piloted.

Members had a long discussion about the number of new expensive treatments reviewed at meetings, the lack of head-to-head of data, and use of agents in patient groups for which there is no evidence. New agents are usually proportionately more expensive than anything that it is replacing/we are no longer using.

Members touched on the financial implications, financial governance and affordability of the access to new medicines agenda. Members accepted that, although not a simple discussion, there is a need to open a dialogue about budget, particularly where there are direct choices where one costs significantly less than the other and does not disadvantage the patient.

The Group requested a breast cancer specialist attend a future meeting to discuss the submissions for tucatinib and trastuzumab deruxtecan, and breast cancer pathways.
It was noted that the breast cancer service is very busy at the moment, as a significant amount of mutual aid is being provided to NHS Tayside.

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The Group deferred decision-making for tucatinib and trastuzumab deruxtecan to a future meeting.

SMC 2398 - Tucatinib 50mg, 150mg film-coated tablets (Tukysa®) ▼ decision deferred to a future meeting.
Indication under review: in combination with trastuzumab and capecitabine for the treatment of adult patients with HER2-positive locally advanced or metastatic breast cancer who have received at least two prior anti-HER2 treatment regimens.
In a phase II study the addition of tucatinib to trastuzumab plus capecitabine was associated with a statistically significant improvement in progression-free survival.
This advice takes account of the views from a Patients and Clinician Engagement (PACE) meeting.
This advice applies only in the context of an approved NHS Scotland Patients 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.
Decision deferred to a future meeting. **FTEAM**

SMC 2388 - Trastuzumab deruxtecan 100mg powder for concentrate for solution for infusion (Enhertu®) ▼ decision deferred to a future meeting.
Indication under review: as monotherapy for the treatment of adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received two or more prior anti-HER2-based regimens.
In an open-label single-arm phase II study trastuzumab deruxtecan was associated with clinically relevant overall response rates in adults with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens.
This advice takes account of the views from a Patients and Clinician Engagement (PACE) meeting.
This advice applies only in the context of an approved NHS Scotland Patients 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.
Decision deferred to a future meeting. **FTEAM**

8.4. FG1SMC 2367 - OLAPARIB (MAINTENANCE TREATMENT OF PLATINUM-SENSITIVE RELAPSED OVARIAN CANCER)

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

The Group considered the request for olaparib monotherapy as maintenance treatment of adults with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy.

The Group noted:

- olaparib:
  - was the first PARP inhibitor to receive a marketing authorisation in the UK, initially it was available as a capsule however this formulation has been discontinued and replaced by a tablet formulation
  - [as the capsule], is only licensed as monotherapy for maintenance in the relapsed setting (this indication) and is included on the formulary
  - [as the tablet] has multiple licences for ovarian cancer and other cancers (breast, pancreatic, prostate), currently only first-line maintenance treatment of BRCA-mutated advanced ovarian cancer (SMC 2209) is accepted to formulary
  - is now used in the first-line maintenance setting meaning that use in the relapsed setting [this indication] will decrease with time

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- patient benefits:
  - lower pill burden for tablets (100mg/150mg versus 50mg capsules)
  - the tablets can be taken with food or between meals, whereas the capsules cannot
- the SMC advice takes account of the benefits of a complex PAS that improves the cost-effectiveness of olaparib

The Group accepted the restricted local need for olaparib, as the tablet formulation, as monotherapy for the maintenance treatment of adults with BRCA-mutated (germline and/or somatic) platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy, as outlined in SMC 2367.

SMC 2367 - Olaparib 100mg, 150mg film-coated tablets (Lynparza®) is routinely available in line with national guidance (SMC 2367).
Indication under review: as monotherapy maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer.
Olaparib hard capsules were previously accepted for use within NHS Scotland under the ultra-orphan and end of life process as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy.
Olaparib film-coated tablets will replace olaparib capsules, which are to be discontinued.
Olaparib film-coated tablets demonstrated higher bioavailability compared to olaparib capsules and therefore a dose adjustment is required when switching from capsules to film-coated tablets.
This advice applies only in the context of an approved NHS Scotland Patients 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 use of anti-cancer medicinal products. **FTEAM**

SMC 1047/15 - Olaparib 50mg capsules (Lynparza®) is now withdrawn from use/discontinued.
Indication: monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy.
This medicine is now withdrawn from use/discontinued. **FTEAM**

8.5. FG1SMC 2353 - 5-AMINOLEVULINIC ACID MEDICATED PLASTER (ACTINIC KERATOSES LESIONS)

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

The Group considered the request for 5-aminolevulinic acid medicated plaster for single use treatment of mild actinic keratoses (AK) lesions with a maximum diameter of 1.8cm on the face and scalp (hairless areas).

The Group noted:
- 5-aminolevulinic acid is a photosensitising agent used in photodynamic therapy (PDT)
- 5-aminolevulinic acid medicated plaster (Alacare®):

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- is a single application 'ready-to-use' self-adhesive plaster formulation of 5-aminolevulinic acid with a 4cm^2 treatment area per plaster
- up to a maximum of six Alacare® plasters can be used on six different lesions (24cm^2 treatment area) in a single treatment session
- is licensed for mild AK, small lesions only (maximum diameter 1.8cm)
- does not require curettage before application, however the skin may be cleaned with isopropanol or ethanol before application if necessary
- does not need a covering dressing after application
- has a 4-hour application time, with no cleaning after plaster removal

- lesion responses should be assessed after three months. If the area treated with Alacare® is not lesion free at 3 months [following single use] alternative therapies for removal of AK lesions should be used.
- patient numbers are expected to be small but may increase with time
- if a patient was using both Alacare® and Ameluz® the service would apply Alacare® plaster(s) first then apply Ameluz® to the other sites. On return to the clinic the Ameluz® sites would be cleaned first and the Alacare® plaster(s) removed later to offset the additional hour application time required for Alacare®.
- the service plans to use Alacare® for small lesions on tricky sites such as around the eyes and lips

The Group accepted the restricted local need for 5-aminolevulinic acid medicated plaster for single use treatment of mild actinic keratoses lesions, as outlined in SMC 2353. Members noted that the service would only use Alacare® on small lesions on tricky sites such as round the eyes and lips.

SMC 2353 - 5-aminolevulinic acid 8mg medicated plaster (Alacare®) is routinely available in line with national guidance (SMC 2353).
Indication under review: single use treatment of mild actinic keratoses lesions with a maximum diameter of 1.8cm on the face and scalp (hairless areas).
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. FTEAM

8.6. FG1SMC 2403 - TRALOKINUMAB (ATOPIC DERMATITIS)

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

The Group considered the request for tralokinumab for the treatment of moderate to severe atopic dermatitis in adults who are candidates for systemic therapy who have had an inadequate response to an existing systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable.

The Group noted:

- tralokinumab
  - is a monoclonal antibody given by subcutaneous injection every other week – initially 600mg (four injections) followed by 300mg (two injections) – if appropriate patients can self-inject
  - has therapeutic effect assessed at 16 weeks and frequency reduced to every 4 weeks for patients with clear skin or stopped if no response
  - is more effective than placebo at reducing the extent and severity of atopic dermatitis after 16 weeks of treatment, no head-to-head data versus other biologics
- patient numbers are expected to be small
- the service plans to supply via Homecare if patient can self-inject
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of tralokinumab
- alternative 'biologics' are also subject to PASs, and placement will be as an alternative to dupilumab (monoclonal) or baricitinib (JAK inhibitor)
- the three agents have different sites/mechanisms of action

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- these are long-term treatments, and costs will be cumulative

The Group accepted the restricted local need for tralokinumab for the treatment of moderate to severe atopic dermatitis in adults, as outlined in SMC 2403.

SMC 2403 - Tralokinumab 150mg solution for injection in pre-filled syringe (Adtralza®) ▼ is routinely available in line with national guidance (SMC 2403).
Indication under review: for the treatment of moderate to severe atopic dermatitis in adults who are candidates for systemic therapy who have had an inadequate response to an existing systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable.
Four phase III studies demonstrated superiority of tralokinumab in improving signs and symptoms of atopic dermatitis when compared with placebo, as monotherapy or in combination with topical corticosteroids in patients with moderate to severe atopic dermatitis.
This advice applies only in the context of an approved NHS Scotland Patients 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 healthcare professionals experienced in the diagnosis and treatment of atopic dermatitis. **FTEAM**

8.7. UMAR SMC 2413 - ATIDARSAGENE AUTOTEMCEL (METACHROMATIC LEUKODYSTROPHY)

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

Ms Doney confirmed that:

- atidarsagene autotemcel (Libmeldy®) has been validated as meeting SMC ultra-orphan (UO) criteria 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.
- SG will notify Health Boards when Libmeldy® is available for prescribing within the ultra-orphan pathway. Meantime any requests to access treatment should be considered through local non-formulary processes.
- until notification from SG, Libmeldy® will be recorded as '*Not routinely available in NHS Grampian however if local need is identified: Contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI)*'.
- when available for prescribing within the ultra-orphan pathway is confirmed the formulary advice will be changed to '*Not routinely available in NHS Grampian however if local need is identified: Treatment is available through the National Services Scotland Ultra-Orphan Medicines Risk Share Scheme'*.

In line with local processes, the Group recorded Libmeldy® [SMC 2413] as non-formulary.

SMC 2413 - Atidarsagene autotemcel 2 to 10 x 10^6 cells/mL dispersion for infusion (Libmeldy®) ▼ is not routinely available in NHS Grampian.
Indication under review: treatment of metachromatic leukodystrophy (MLD) characterized by biallelic mutations in the arylsulfatase A (ARSA) gene leading to a reduction of the ARSA enzymatic activity:

- **in children with late infantile or early juvenile forms, without clinical manifestations of the disease,**
- **in children with the early juvenile form, with early clinical manifestations of the disease, who still have the ability to walk independently and before the onset of cognitive decline.**

Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI). **FTEAM**

ITEM	SUBJECT	ACTION

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED MAY 2022

The Group noted the SMC provisional advice issued May 2022.

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

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS – PUBLISHED MAY 2022

The Group noted the SMC advice published May 2022.

Following publication of the negative SMC recommendations, for ropeginterferon alfa-2b (Besremi®)▼ SMC 2421 and daratumumab (Darzalex®) SMC 2416, and the non-submission statements, for mepolizumab (Nucala®) SMC 2488, SMC 2490, SMC 2491 and cemiplimab (Libtayo®)▼ SMC 2489, 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 2420 pembrolizumab (Keytruda®) (submission received)
- SMC 2428 dapagliflozin (Forxiga®) (submission expected)
- SMC 2427 venetoclax (Venclyxto®)▼ (submission received)
- SMC 2429 nivolumab (Opdivo®) (submission expected)
- SMC 2455 liraglutide (Saxenda®) (submission expected)
- SMC 2285 oritavancin (Tenkasi®) (clinicians not responded)
- SMC 2467 filgotinib (Jyseleca®)▼ (submission received)

Local advice for these medicines and indications will be included in the May 2022 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

LIRAGLUTIDE (SAXENDA®)

Ms Doney reported that NHS Grampian will issue a holding statement for liraglutide as the brand Saxenda® for weight management.

Liraglutide is already included on the formulary for Type 2 diabetes as the brand Victoza®. The SMC advice for Saxenda® will need to go through local processes before it can be considered for prescribing locally. The SMC advice restricts use to a sub-group of the licensed population and patients should be treated in a specialist weight management service.
Saxenda® is being prescribed by private clinics but this use may not be in line with the SMC restriction.
Specialists have been contacted and a submission is expected.

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM – MAY 2022

EMTRICITABINE/TENOFOVIR ALAFENAMIDE (DESCOVY®)

Ms Doney reported that the SMC has advised that Descovy® 200/25 tablets, for pre-exposure prophylaxis (PrEP), is considered outwith remit.
The Formulary Team will liaise with the specialist service to confirm if there is a local need for this preparation in a niche of patients.

ITEM	SUBJECT	ACTION

12. DOCUMENTS FOR INFORMATION

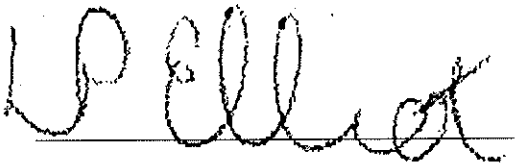
Items 12.1 (Drug Safety Update April 2022), 12.2 (Antimicrobial Management Team minute February 2022), and 12.3 (Medicine Guidelines and Policies Group minute November 2021) were noted.

13. AOCB

NONE.

DATE OF NEXT MEETING

Tuesday 21 June 2022 starting at 14.30 via Microsoft Teams

CHAIR'S SIGNATURE  **DATE 21 JUNE 2022**