NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 17 September 2024 at 14:30 via Microsoft Teams

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

IN ATTENDANCE
Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team.

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 20 AUGUST 2024

Members accepted the draft note of the meeting subject to minor typographical changes.

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

2.2. FORMULARY GROUP DECISIONS AUGUST 2024 - PUBLISHED 02/09/2024

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

3. MATTERS ARISING

3.1. Action LOG

The action log was noted.

3.2. DARA-VTD (MULTIPLE MYELOMA)

The Chair confirmed that Dara-VTD, (daratumumab plus bortezomib, thalidomide and dexamethasone) for the treatment of adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant, will remain on the formulary for patients who are intolerant of lenalidomide.

3.3. TOPIRAMATE NEW SAFETY MEASURES - UPDATE

Ms Doney confirmed that the local valproate Short Life Working Group (SLWG) now includes topiramate. The SLWG will consider the requirements of the topiramate pregnancy prevention programme and co-ordinate identification of patients.
The SLWG has not met since July, so topiramate will remain on the action log meantime. **FTEAM**

ITEM	SUBJECT	ACTION

4. PRESENTATION/DISCUSSION

None.

5. NEW PRODUCT REQUESTS

5.1. SMC 2635 - DOSTARLIMAB (dMMR/MSI-H PRIMARY ADVANCED OR RECURRENT ENDOMETRIAL CANCER)

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

The Group considered the request for dostarlimab in combination with platinum-containing chemotherapy for the treatment of adults with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer who are candidates for systemic therapy.

The Group noted that:

- dostarlimab:
  - [for this indication] was accepted for use in NHS Scotland following a full submission. It was eligible for an interim acceptance decision option, and meets SMC end of life and orphan equivalent criteria for this indication, i.e., eligible for PACE. However, neither process was used to support decision-making.
  - is a monoclonal antibody which blocks the programmed cell death protein 1 (PD-1) receptor increasing the immune system's ability to kill the cancer cells
  - [for this indication] is given at a recommended dose of 500mg every 3 weeks for 6 cycles followed by 1000mg every 6 weeks for all cycles thereafter; given as an intravenous infusion (using an intravenous infusion pump over 30 minutes)
  - is continued until disease progression, unacceptable toxicity or up to three years
- endometrial cancer is the sixth most common cancer in women worldwide. It has one of the highest observed rates of dMMR/MSI-H.
- although most endometrial carcinomas are diagnosed at an early stage, up to 15% recur and approximately 20% of patients have advanced or metastatic disease at diagnosis
- the usual treatment for primary advanced or recurrent endometrial cancer with dMMR/MSI-H is platinum-based chemotherapy. The prognosis is poor for people with this condition.
- evidence comes from RUBY-1, a phase III, randomised, double-blind, placebo-controlled study, that investigated the combination of dostarlimab with platinum-based chemotherapy (carboplatin and paclitaxel; n = 245) versus platinum-based chemotherapy (n = 249) alone in patients with primary advanced or recurrent endometrial cancer
  - the two co-primary outcomes were:
    1) progression-free survival (PFS) in subjects with dMMR/MSI-H primary advanced or recurrent endometrial cancer and in all subjects with primary advanced or recurrent endometrial cancer,
    2) overall survival (OS) in all subjects with primary advanced or recurrent endometrial cancer
  - at interim analysis, after a median follow-up of 25 months, showed the PFS not reached (versus 7.7 months in the chemotherapy-only group); OS not reached and not yet conclusive
- there are a lack of long-term data, longer follow-up is needed to fully assess long-term outcomes such as OS and durability of response
- [for this indication] NICE concluded that *clinical trial evidence shows that adding dostarlimab to usual treatment increases how long people have before their condition gets worse. Evidence suggests it also increases how long they live, but the long-term benefits are uncertain because the study only followed people for a short period of time.*

ITEM	SUBJECT	ACTION

- patient numbers are expected to be small, and there will be cost-offset available from dostarlimab moving from second-line
- testing for MMR/MSI status is required to select eligible patients for treatment, and is routinely available in NHS Grampian
- the inclusion criteria for RUBY-1 will be used to assess eligibility for treatment
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of dostarlimab

The Group accepted the restricted local need for dostarlimab in combination with platinum-containing chemotherapy for the treatment of adults with dMMR/MSI-H primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy.

SMC 2635 - Dostarlimab 500mg concentrate for solution for infusion (Jemperli®)▼ is routinely available in line with national guidance (SMC 2635).
Indication under review: in combination with platinum-containing chemotherapy for the treatment of adults with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy.
In a double-blind, randomised, phase III study, progression-free survival was significantly improved with dostarlimab in combination with platinum-containing chemotherapy compared with platinum-containing chemotherapy alone in patients with dMMR/MSI-H primary advanced or recurrent endometrial cancer.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Therapy must be initiated and supervised by specialist physicians experienced in the treatment of cancer. The identification of dMMR/MSI-H tumour status should be determined using a validated testing method such as immunohistochemistry, polymerase chain reaction or next-generation sequencing. FTEAM

5.2. SMC 2615 - IVOSIDENIB (NEWLY DIAGNOSED ACUTE MYELOID LEUKAEMIA (AML))

Dr Culligan declared a personal, non-specific interest in Servier Laboratories Limited and took part in the discussion and decision-making.

The Group considered the request for ivosidenib in combination with azacitidine for the treatment of adults with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who are not eligible to receive standard induction chemotherapy.

The Group noted that:
- ivosidenib:
  - [for this indication] meets SMC end of life and orphan criteria and was accepted for use only in the context of the SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios and the output from the PACE process
  - is an inhibitor of mutant IDH1 enzyme, and its mechanism of action is not fully understood
- AML is an aggressive, rapidly progressing malignancy characterised by clonal proliferation of myeloid blast cells in the bone marrow and often in the peripheral blood and other tissues. IDH1 mutations are associated with poor prognosis.
- current practice for patients who are not eligible to receive standard induction chemotherapy is azacitidine plus venetoclax, and this request seeks to replace venetoclax with ivosidenib, only for patients with a confirmed IDH1 R132 mutation
- June 2024, NICE recommended ivosidenib plus azacitidine, within its marketing authorisation, as an option for untreated AML with an IDH1 R132 mutation in adults

who cannot have standard intensive induction chemotherapy, TA979

- evidence comes from AGILE (n=146), a randomised, multicentre, double-blind, placebo-controlled phase III study, which evaluated the efficacy and safety of ivosidenib in combination with azacitidine versus placebo-azacitidine:
  - the primary efficacy endpoint was event-free survival (EFS), measured from the date of randomisation until treatment failure, relapse from remission, or death by any cause. Treatment failure was defined as failure to achieve complete remission (CR) by week 24.
  - the study was stopped early, and the unplanned efficacy analyses (at data cut-off 18 March 2021) became the primary analysis. The primary and key secondary outcomes appear improved with ivosidenib-azacitidine compared with placebo-azacitidine.
  - an updated OS analysis (data cut-off 30 June 2022), at median follow-up of 28.6 months confirmed the OS benefit – within the ivosidenib and placebo groups, median OS was 29.3 versus 7.9 months, respectively, with a hazard ratio (HR) of 0.42 (95% confidence interval [CI]: 0.27 to 0.65). Estimated OS rates were 63% versus 38% at 12 months; and 53% versus 17% at 24 months in the respective groups.
- limitations of the data:
  - early study discontinuation may have an impact on the estimates of OS benefit at the primary analysis and crossover may confound subsequent OS analysis
  - there are no direct data comparing ivosidenib-azacitidine versus venetoclax-azacitidine
  - relative efficacy compared with venetoclax-azacitidine was estimated from an indirect treatment comparison which had several limitations. The SMC states that the results do not support a conclusion of superiority for ivosidenib-azacitidine, compared with venetoclax-azacitidine for both EFS and OS.
- NICE TA979 noted that:
  - an indirect comparison suggests that ivosidenib plus azacitidine increases how long people live and how long they have before their condition gets worse compared with venetoclax plus azacitidine
  - the most likely cost-effectiveness estimates for ivosidenib plus azacitidine are within the range that NICE considers an acceptable use of NHS resources
- patient numbers are expected to be very small
- before taking ivosidenib, patients must have confirmation of an IDH1 R132 mutation using an appropriate diagnostic test. Locally, IHD1 mutation testing may take up to four weeks to be reported, patients may start one cycle of azacitidine-venetoclax and then switch to ivosidenib-azacitidine.
- patients would be offered the ivosidenib-azacitidine regimen if they had the IHD1 mutation due to the better side effect profile [than venetoclax-azacitidine]
- treatment should be continued until disease progression or until treatment is no longer tolerated by the patient
- azole antifungals are given as standard, so patients will receive the 250mg daily dose
- cost offset is available from the displacement of venetoclax
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ivosidenib
- all newly diagnosed AML patients are admitted to hospital because they are unwell, and may be in hospital for a few weeks

The Group accepted the restricted local need for ivosidenib in combination with azacitidine for the treatment of adults with newly diagnosed AML with an IDH1 R132 mutation who are not eligible to receive standard induction chemotherapy.

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	SMC 2615 - Ivosidenib 250mg film-coated tablet (Tibsovo®)▼ is routinely available in line with national guidance (SMC 2615). **Indication under review: in combination with azacitidine for the treatment of adults with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who are not eligible to receive standard induction chemotherapy.** **Addition of ivosidenib to azacitidine improved event-free and overall survival in untreated adults with newly diagnosed AML and IDH1 R132 mutation who were ineligible for intensive induction chemotherapy.** **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.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.** **Treatment should be initiated under the supervision of physicians experienced in the use of anti-cancer medicinal products.** **Before taking ivosidenib, patients must have confirmation of an IDH1 R132 mutation using an appropriate diagnostic test.**	**FTEAM**

5.3. SMC 2618 - MAVACAMTEN (OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY (OHCM))

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

Members discussed the SMC Detailed Advice Document for mavacamten hard capsules, for the treatment of symptomatic (New York Heart Association, NYHA, class II to III) obstructive hypertrophic cardiomyopathy (oHCM) in adults.

Ms Doney confirmed that a full review was not undertaken as there are significant service implications related to the introduction of mavacamten. Patients should be genotyped for Cytochrome P450 (CYP) 2C19 (CYP2C19) in order to determine the appropriate mavacamten dose, and echocardiograms need to be regularly conducted to monitor left ventricular ejection fraction (prior to initiating treatment and during treatment).

Accepting that these are complex patients under the care of Cardiologists, members agreed to defer the review of the submission until there is more information about the potential service impacts, particularly availability of CYP2C19 testing and capacity to undertake echocardiograms, with clarity of how the medicine will be used and titrated and a potential patient pathway.

6. FORMULARY REVIEW

6.1. FORMULARY REVIEW - INTRAUTERINE PROGESTOGEN-ONLY DELIVERY SYSTEMS

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

The Group considered the information provided by the Formulary Team to support review of the levonorgestrel-containing intrauterine delivery systems (LNG-IUSs) formulary sub-section.

The Group noted that:

- following the August meeting the contraception licence for Benilexa® One Handed was extended to 8 years, i.e., in line with the other 52mg LNG-IUSs
- the Faculty of Sexual and Reproductive Healthcare (FSRH) supports the use of any 52mg LNG-IUS for up to 5 years for endometrial protection in individuals using oestrogen as part of HRT. Only Mirena® is licensed for this indication, licensed for 4 years, so use to 5 years for any 52mg LNG-IUS would be off-label.

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Mirena® and Levosert® are already included on the formulary for 5 years for this indication.

- the licence wording for Mirena® and Levosert®, when used for idiopathic menorrhagia, have changed and now state that the devices can continue to be used beyond their clinical efficacy data if symptoms do not return:
  - Mirena® - the SmPC states *Mirena® is effective for 5 years and clinical data beyond 5 years of use are limited, return of symptoms may indicate reduced efficacy. The system should be removed or replaced in case symptoms return. If symptoms have not returned after 5 years of use, continued use of the system may be considered. Remove or replace no later than 8 years after insertion*.
  - Levosert® and Benilexa® – the SmPCs state that the devices are effective for 3 years, with advice that they should be removed or replaced if symptoms return. The device may be used for more than 3 years if symptoms are controlled and removed or replaced no later than 8 years after insertion.
- Kyleena® and Jaydess® are only licensed for contraception, 5 years and 3 years respectively, and there are no major changes to their SmPCs
- the formulary includes a statement that LNG-IUSs should always be prescribed by brand name because the products have different indications, durations of use, and introducers. Members supported altering the wording to '*Prescribed by brand name to prevent confusion between products*.'

The Group accepted the Benilexa® One Handed contraception licence extension to 8 years.
The Group noted the wording changes to the 52mg LNG-IUSs licences for heavy menstrual bleeding, and backed the FSRH position supporting the off-label use of any 52mg LNG-IUS as endometrial protection for 5 years for individuals using oestrogen as part of HRT.

Members supported the suggested changes to the formulary entries and requested that the FSRH supported off-label indications are highlighting in the prescribing notes on the formulary. **FTEAM**

Levonorgestrel 52mg (20micrograms/24 hours) Intrauterine Delivery System (Benilexa® One Handed) is routinely available in line with local guidance.
Indications under review:

- **contraception for 8 years (licence extension)**
- **heavy menstrual bleeding, efficacy data for 3 years. The device may be used for more than 3 years if symptoms are controlled, and removed or replaced no later than 8 years after insertion.**

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).
Indication under review: [off-label] as endometrial protection for 5 years for individuals using oestrogen as part of hormone replacement therapy (HRT)
It was classified 3b - licensed product requested for unlicensed use and 8e - treatment may be initiated in either Primary or Secondary care. **FTEAM**

Levonorgestrel 52mg (20micrograms/24 hours) Intrauterine Delivery System (Levosert®) is routinely available in line with local guidance.
Indication under review: heavy menstrual bleeding, efficacy data for 3 years. The device may be used for more than 3 years if symptoms are controlled, and removed or replaced no later than 8 years after insertion.
It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care. **FTEAM**

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Levonorgestrel 52mg (20micrograms/24 hours) Intrauterine Delivery System (Mirena®) is routinely available in line with local guidance.
Indication under review: idiopathic menorrhagia, efficacy data for 5 years. The device may be used for more than 5 years if symptoms are controlled, and removed or replaced no later than 8 years after insertion.
It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care. **FTEAM**

6.2. OLIVE OIL FOR CRADLE CAP

Members considered the information shared by the Formulary Pharmacist for the East Region Formulary regarding the use of olive oil for cradle cap.

Noting the information considered by the East Region Working Group and that nationally supported patient resources, e.g., NHS Inform and The NHS website for England, no longer advocate the use of olive oil as a treatment for cradle cap.

Members agreed that the formulary should align with NHS Inform and supported removal of olive oil from the formulary and the Pharmacy First Approved List for cradle cap. **FTEAM**
Removal is subject to support from the local Health Visitors and further investigation to confirm which products are suggested for baby massage. **GMCK**

6.3. ROXADUSTAT (UPDATE)

Ms Doney reported that previously roxadustat was classified as '8c - treatment to be initiated in hospital prior to handover'. However, following discussion between other NHS Grampian Groups and the Renal Service and it has been decided that any patients to be prescribed roxadustat will, at this moment, be managed within renal acute services.

To align with the work done locally the Group accepted the reclassification of roxadustat to 'recommended for hospital use only'.

SMC 2461 - Roxadustat 20mg, 50mg, 70mg, 100mg, 150mg film-coated tablets (Evrenzo®)▼ is routinely available in line with national guidance (SMC 2461).
Indication under review: treatment of adults with symptomatic anaemia associated with chronic kidney disease (CKD) who are non-dialysis dependent (NDD) at the time of treatment initiation.
Roxadustat was non-inferior to an erythropoiesis stimulating agent and superior to placebo for improving haemoglobin levels in adults with anaemia in CKD who were NDD.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme 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 with roxadustat should be initiated by a physician experienced in the management of anaemia. All other causes of anaemia should be evaluated prior to initiating therapy with roxadustat, and when deciding to increase the dose. **FTEAM**

6.4. SMC COLLABORATION WITH NICE ON TA988: IVACAFTOR/TEZACAFTOR/ELEXACAFTOR, TEZACAFTOR/IVACAFTOR AND LUMACAFTOR/IVACAFTOR FOR TREATING CYSTIC FIBROSIS

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

Members ratified the SMC/NICE Collaborative Advice Documents for ivacaftor-tezacaftor-elexacaftor (Kaftrio®), tezacaftor-ivacaftor (Symkevi®) and lumacaftor-ivacaftor (Orkambi®).

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	SMC 2711 - Symkevi® 50mg/75mg, 100mg/150mg film-coated tablets (tezacaftor/ivacaftor) is routinely available in line with national guidance (TA988). **Indication under review: for use in a combination regimen with ivacaftor tablets for the treatment of people with cystic fibrosis (CF) aged 6 years and older who have:** • **2 copies of the CFTR gene with *F508del* mutations, or** • **a copy of the CFTR gene with an *F508del* mutation and a copy of the CFTR gene with 1 of the mutations listed - *P67L, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G*, and *3849+10kbC→T*** **The 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.** **Symkevi® should only be prescribed by physicians with experience in the treatment of CF. If the patient's genotype is unknown, an accurate and validated genotyping method should be performed to confirm the presence of an indicated mutation using a genotyping assay.**	**FTEAM**
	SMC 2712 - Orkambi® 100mg/125mg, 200mg/125mg film-coated tablets, 75mg /94mg, 100mg/125mg, 150mg/188mg granules in sachets (lumacaftor/ivacaftor) is routinely available in line with national guidance (TA988). **Indication under review: for the treatment of cystic fibrosis (CF) in people aged 1 year and older who have 2 copies of the cystic fibrosis transmembrane conductance regulator (CFTR) gene with *F508del* mutations.** **The 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.** **Orkambi® should only be prescribed by physicians with experience in the treatment of CF. If the patient's genotype is unknown, an accurate and validated genotyping method should be performed to confirm the presence of the *F508del* mutation on both alleles of the CFTR gene.**	**FTEAM**
	SMC 2713 - Kaftrio®▼ 37.5mg/25mg/50mg, 75mg/50mg/100mg film coated tablets, 60mg/40mg/80mg, 75mg/50mg/100mg granules (elexacaftor/ivacaftor/tezacaftor) is routinely available in line with national guidance (TA988). **Indication under review: for use in a combination regimen with ivacaftor for the treatment of cystic fibrosis (CF) in people aged 2 years and older who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.** **The 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.** **Kaftrio® should only be prescribed by healthcare professionals with experience in the treatment of CF. If the patient's genotype is unknown, an accurate and validated genotyping method should be performed to confirm the presence of at least one *F508del* mutation using a genotyping assay.**	**FTEAM**

6.5. DISCONTINUATIONS

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

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Ms Doney reported that

- GlaxoSmithKline UK will discontinue mepolizumab 100mg powder for solution for injection (Nucala®) on the 30th September 2024. GSK will focus on distribution of the more convenient, prefilled syringe adult formulations (100mg pre-filled syringe/pen), and the paediatric presentation (40mg pre-filled syringe).
- Fresenius Kabi limited have confirmed the discontinuation of Glandosane® artificial saliva spray. The decision was not due to a safety concern and the marketing authorisation has not been passed to another company.

Ms Doney confirmed that the discontinuations are considered low impact withdrawals, mepolizumab will remain available in other formulations and alternative artificial saliva products are available.

Members requested that the Palliative Care pharmacist is contacted for advice on alternative/preferred artificial salvia products. **FTEAM**

Members supported updating the formulary noting the withdrawals/discontinuations. **FTEAM**

7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED SEPTEMBER 2024

The Group noted the SMC advice published September 2024.

Following publication of the non-submission statements, for pegcetacoplan (Aspaveli®)▼ SMC 2715, volanesorsen (Waylivra®)▼ SMC 2716 and zilucoplan (Zilbrysq®)▼ SMC 2717, 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 2667 dabrafenib (Finlee®)
- SMC 2669 elranatamab (Elrexfio®)▼
- SMC 2664 ivosidenib (Tibsovo®)▼
- SMC 2668 teclistamab (Tecvayli®)▼

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

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED SEPTEMBER 2024

The Group noted the SMC provisional advice issued September 2024.

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

SMC 2725 - DROSPIRENONE 4MG FILM-COATED TABLETS (SLYND®)

Ms Doney highlighted the 'non-submission' provisional advice for Slynd®, a drospirenone-only progestogen-only pill (POP).

Ms Doney confirmed that:

- Slynd® has a different dose regimen to other contraceptive pills, consisting of twenty-four tablets and four inactive tablets in each 28-day cycle
- drospirenone is derived from spironolactone and has antiandrogenic and

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antimineralocorticoid properties, and its risk of venous thromboembolism is not known
- Slynd® is more expensive than, and has no efficacy data versus levonorgestrel, but potentially has a higher risk of thromboembolism, hyperkalaemia and cardiac arrhythmia
- after publication of the SMC advice Slynd® will be noted as non-formulary
- the service is aware of the provisional SMC advice

ADDITIONAL ITEM NOT INCLUDED ON THE AGENDA.

The Chair confirmed that draft NCMAG guidance is expected for anastrozole, raloxifene and tamoxifen for the primary prevention of breast cancer in post-menopausal women at moderate to high risk. It is not known if implementation guidance will be issued with the NCMAG reviews.

As these patients do not have breast cancer, and are not necessarily under specialist service, members discussed which professionals the draft advice should be shared with.

Members considered this would be an interesting scenario to have a round table discussion with the breast surgeons, geneticists, menopause clinic/gynaecologists, pharmacists and GPs/Primary Care prescribers.

9. OTHER BUSINESS

9.1. SMC VISITING ADTCS

The Chair reported that Dr Scott Muir and Dr Yvonne Semple (Chair and Vice-Chair of the SMC) are scheduled to attend the November Grampian Area Drug and Therapeutics Committee (GADTC) meeting to update on the work of the SMC, enable discussion around issues of common interest and receive feedback on how SMC can further collaborate with ADTCs.
Formulary Group members are welcome to join the meeting for the presentation and discussion, members that wish to join the meeting should email Ms Doney. **ALL**

10. DOCUMENTS FOR INFORMATION

Items 10.1 (Drug Safety Update August 2024), 10.2 (MedWatch September 2024), 10.3 (Antimicrobial Management Team minute July 2024) and 10.4 Medicines Guidelines and Policies Group minute July 2024) were noted.

11. AOCB

CONSENSUS STATEMENT GLP-1/ GIP RAS FOR THE TREATMENT OF OBESITY IN NHS SCOTLAND

Ms Doney reported that the consensus statement GLP-1/ GIP RAs for the treatment of obesity in NHS Scotland is now published and the link will be shared after the meeting. **FD**

The formulary position remains the same non-formulary (not routinely available as local implementation plans are being developed).

DATE OF NEXT MEETING

Tuesday 15 October 2024 starting at 14.30 via Microsoft Teams

Dr Louise Elliot

CHAIR'S SIGNATURE **Signature on file** **DATE 15 OCTOBER 2024**