NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 19 November 2024 at 14:30 via Microsoft Teams

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

IN ATTENDANCE

Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team.
Professor Abha Maheshwari, Clinical Lead and Director Reproductive Medicine Aberdeen Fertility Centre, for item 4.
Dr Laxmi Shingshetty, Sub-Specialist Trainee in Reproductive Medicine, for item 4.
Mrs Laura Stephen, Senior Charge Nurse, Medicine Aberdeen Fertility Centre, for item 4.

Note some items were taken outwith agenda order.

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.

4. PRESENTATION/DISCUSSION

The Chair welcomed Professor Maheshwari and Dr Shingshetty to the meeting to discuss the request for follitropin delta (Rekovelle®) as an additional gonadotropin for use in controlled ovarian stimulation in women undergoing assisted reproductive technologies.

The requestors confirmed that:

- in IVF (in vitro fertilisation), external hormones (gonadotrophins) are given to stimulate a person's ovaries to increase the number of eggs produced. This allows doctors to collect many eggs from which they can generate embryos and select ones with the best chances of pregnancy, improving the chances of a live birth.
- although ovarian stimulation is generally well controlled it can go uncontrolled and lead to hyperstimulation where patients can become ill and it can be life-threatening
- although there are tests that can be used to 'predict' the type of drugs a person needs to minimise the chance of hyperstimulation, these are only predictors and not 100% accurate
- ovarian hyperstimulation:
  - is a potentially serious complication of fertility treatment, particularly of IVF
  - is a risk to the patient because the ovarian blood vessels leak fluid. This fluid swells the ovaries, and sometimes large amounts move into the abdomen so there

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is fluid collection in the abdomen and sometimes the chest.
    - symptoms range from mild to severe. Mild ovarian hyperstimulation is common and usually gets better with time. More severe cases require specialist care and hospital admission.
      In severe cases patients require multiple days of admission. Patients can present with bloating/ascites, difficulty breathing (because of the build-up of fluid in the chest). Patients may also suffer with the formation of blood clots in the lungs or elsewhere.
- traditionally with IVF, the eggs are collected from the ovaries, mixed with sperm for fertilization, embryos are grown in the laboratory and the embryos are transferred within the same week (fresh embryo transfer). However, if there is a risk of ovarian hyperstimulation all of the embryos are frozen and the patient has to come back to use the embryos, so treatment is delayed and incurs additional costs.
- follitropin delta (Rekovelle®) has a different dosing regimen. Dosing is personalised using the patient's weight and anti-Müllerian hormone (AMH) level with the dose calculated using an App.
- the service plans to use follitropin delta in selected patients, starting with patients with an AMH level of >35pmol/L, i.e., high risk of producing very many eggs. Treatment will be assessed and in time the level may be reduced to use in those with an AMH level of ≥25pmol/L.
- the Service has undertaken training to be able to use follitropin delta, and feels ready to initiate treatment in selected patients, with careful monitoring
- previously low-dose menotrophin [150] would have been used for people at a risk of hyperstimulation, but even with low-dose there are cases of collecting 45/50 eggs, whereas the optimum number is 15 to 20 at the most
- a meta-analysis has shown that follitropin delta can reduce the risk from 14% to 7%, and the Service plans to use follitropin delta in a very specific population that is at risk of hyperstimulation
- another benefit of having an alternative treatment available is that a patient's treatment would not have to stop due to supply issues [with menotrophin]
- follitropin delta, used for suitably selected cases, would provide the opportunity to do fresh embryo transfer
- an App is available for doctors and nurses to use to calculate the dose of follitropin delta
- when considering the introduction of follitropin delta, the potential for reduced costs of hospitalisation and tests should be considered

A member queried if the Rekovelle® App had been through the Medicines and Healthcare products Regulatory Agency (MHRA) regulatory approval process. Professor Maheshwari will confirm the regulatory status of the App. **AM**

A member highlighted that multiple embryos in long-term storage provides a dilemma for patients and potentially the Health Board.

The Chair thanked Professor Maheshwari, Dr Shingshetty and Mrs Stephen for attending the meeting to clarify the proposed use of Rekovelle®.

Professor Maheshwari, Dr Shingshetty and Mrs Stephen left the meeting before decision-making.

5.1. SMC 2670 - FOLLITROPIN DELTA (REKOVELLE®) (AS CONTROLLED OVARIAN STIMULATION FOR THE DEVELOPMENT OF MULTIPLE FOLLICLES IN WOMEN UNDERGOING ASSISTED REPRODUCTIVE TECHNOLOGY)

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

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Members discussed the request for follitropin delta and noted that the Service initially plan to use it in patients with an AMH level of ≥35 pmol/L, but in time may move to treating patients with a level of ≥25 pmol/L.

The Group accepted that:

- ovarian hyperstimulation is a potentially serious complication of fertility treatment
- severe cases require specialist care and hospital admission
- ovarian hyperstimulation carries a risk of a large egg collection which may result in unused embryos requiring storage for up to 55 years. Having unused embryos requiring storage may provide an ethical issue and organisational risk to the Health Board.
- patients affected by ovarian hyperstimulation have a higher risk of preterm delivery and low birth weight

The Group accepted the restricted local need for follitropin delta (Rekovelle®) as an additional gonadotropin for use in controlled ovarian stimulation in women undergoing assisted reproductive technologies.
Treatment will initially be utilised for 'high responders', and formulary acceptance is subject to confirmation that the Rekovelle® Dose Calculator is registered as a medical device with the MHRA.

SMC 2670 - Follitropin delta 12micrograms/0.36mL, 36micrograms/1.08mL, 72micrograms/2.16mL solution for injection in a pre-filled pen (Rekovelle®) is routinely available in line with national guidance (SMC 2670).
Indication under review: controlled ovarian stimulation for the development of multiple follicles in women undergoing assisted reproductive technologies (ART) such as an in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) cycle.
Restriction: for use in normal responders (patients with an anti-Müllerian hormone level of >5.4 pmol/L) or high responders (patients with an anti-Müllerian hormone level of ≥25 pmol/L).
Follitropin delta offers an additional treatment choice in the therapeutic class of gonadotropins.
This advice applies only in the context of an 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. Treatment should be initiated under the supervision of a physician experienced in the treatment of fertility problems. **FTEAM**

2. MINUTE AND DECISIONS

2.1. DRAFT MINUTE OF THE MEETING HELD 15 OCTOBER 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 OCTOBER 2024 - PUBLISHED 28/10/2024

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

3. MATTERS ARISING

3.1. Action LOG

The action log was noted.

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3.2. SMC 2592 - SECUKINUMAB (ACTIVE MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA)

Last month members accepted secukinumab to formulary for active moderate to severe hidradenitis suppurativa. However, members queried what (and when) stopping rules would be applied, and how often people with hidradenitis suppurativa were reviewed during treatment.

The requestor confirmed that the service endeavours to review:
- patients as close to 16 weeks as possible after starting an interleukin inhibitor. If the patient's condition has deteriorated (primary failure) then treatment would be stopped. If they have improved then treatment continues.
- patients with hidradenitis suppurativa six-monthly while stable on interleukin inhibitors. If the response was not felt to be entirely stable or significant, patients would be seen back earlier, in two to three months, to assess progress.

Item closed. **FTEAM**

3.3. SMC 2610 - RITLECITINIB (SEVERE ALOPECIA IN ADULTS AND ADOLESCENTS)

Last month members accepted ritlecitinib to formulary for the treatment of severe alopecia areata. However, members questioned if people that had stopped treatment due to response would be retreated, and requested clarification that monitoring would be undertaken by the managed service, in clinic and/or at Secondary Care community-hubs.

The requestor confirmed that:
- as the treatment is not a cure, and the condition is unpredictable in its course, it is felt likely that some patients who achieve regrowth and then stop treatment will have recurrence of hair loss. If it did occur, it is not known what proportion of patients this may apply to. There is no specific product contraindication to re-starting treatment due to an earlier course, and no UK guideline that would advise against it, so re-starting treatment would be considered.
- it is currently standard for all the treatments under specialist prescribing at Aberdeen Royal Infirmary (ARI) to be monitored from ARI, subject to resources

Item closed. **FTEAM**

5. NEW PRODUCT REQUESTS

5.2. SMC 2198 - RIBOCICLIB (HR-POSITIVE, HER2-NEGATIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER)

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

The Group considered the request for ribociclib tablets, used in combination with fulvestrant, for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women who have relapsed on or within 12 months of completing (neo) adjuvant endocrine therapy, or who have progressed on first-line endocrine-based therapy for advanced breast cancer.

The Group noted that:
- ribociclib:
  - [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
  - blocks the activity of enzymes known as cyclin-dependent kinases (CDK) 4 and 6, which are important for regulating the way cells grow and divide. By blocking CDK4 and CDK6, ribociclib slows the growth of HR-positive breast cancer cells.

- ribociclib, abemaciclib and palbociclib are all CDK 4/6 inhibitors. The three agents are included on the formulary, as initial endocrine-based therapy, in combination with an aromatase inhibitor for the treatment of postmenopausal adults with HR-positive, HER2-negative locally advanced or metastatic breast cancer.
- November 2019, abemaciclib (in combination with fulvestrant) and palbociclib (in combination with fulvestrant) were accepted to formulary. At the same meeting ribociclib in combination with fulvestrant, i.e., this request, was noted as not preferred due to its increased monitoring requirements [ECG monitoring].
- the evidence shows increased progression-free survival compared with endocrine monotherapy in women with HR-positive, HER2-negative locally advanced or metastatic breast cancer
- patient numbers are expected to be small
- cost offset is available as some costs are already in the system [for abemaciclib and palbociclib]. However additional costs not included, and different to other CDK 4/6 inhibitors, is the need for ECG monitoring.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ribociclib
- the requestor confirmed that:
  - ribociclib is not currently included in the National Clinical Management Guideline (CMG), and the requestor has confirmed that this was an oversight and plans are underway for this to be added to the National CMG
  - there is updated overall survival (OS) data
  - there is sufficient capacity to undertake the required ECG monitoring, with improved access to ECG monitoring via handheld machine

Ms Galvin confirmed that:

- the service could not ignore the updated OS data
- there will be no head-to-head data for the CDK 4/6 inhibitors
- the fulvestrant prescribing information document would be updated if this combination was accepted
- patients will be reviewed monthly initially in clinic and seen by clinical nurse specialists
- this combination is being used in other centres in NHS Scotland, and there is a drive to have this regimen discussed and added to the National Breast Cancer Clinical Management Pathway. There is not a clear timeline for inclusion of ribociclib [plus fulvestrant] in the National Clinical Management Pathway.

Members noted the additional cardiac effects with ribociclib, and considered what safety precautions should be considered. Members felt this was especially important for colleagues in Primary Care, as commonly prescribed medicines that extend the QT interval could be issued to patients by Primary Care prescribers.

Members agreed that due to the very small patient numbers, it was important that the QT interval risk [with ribociclib] is highlighted in communication between the managed service and Primary Care. Members also queried what information would be shared with patients.

Ms Galvin confirmed that patients will be reviewed monthly initially in clinic, and seen by the Breast Cancer Clinical Nurse Specialists with prescribing controlled via Systemic Anti-Cancer Therapy (SACT) protocols. It is not unfamiliar for the service to monitor drugs with these side-effects.

Members discussed how to make sure letters are ‘actionable’ documents for Primary Care, with clear actions for the prescriber, e.g., please pass to your Pharmacotherapy Team, drug X prologues the QT interval, please put warning on patient files/in the patients notes while they are taking this drug.

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Ms Galvin will link the Consultants and Clinical Nurse Specialists to confirm what information is shared with Primary Care [and patients] to highlight the risk of co-prescribing medicines that prolong the QT interval, and, if required, ask for specific text to be added to letters so that the communications are seen as 'actionable' documents for Primary Care. **MG**

The Group accepted the restricted local need for ribociclib, as an additional CDK 4/6 inhibitor, used in combination with fulvestrant for women who have relapsed on or within 12 months of completing (neo) adjuvant endocrine therapy, or those who have progressed on first-line endocrine-based therapy for advanced breast cancer. Formulary inclusion is subject to update of the local Fulvestrant Information Sheet.

SMC 2198 - Ribociclib 200mg film-coated tablets (Kisqali®) is routinely available in line with national guidance (SMC 2198).
Indication under review: for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy.
Restriction: women who have relapsed on or within 12 months of completing (neo) adjuvant endocrine therapy, or those who have progressed on first-line endocrine-based therapy for advanced breast cancer.
Ribociclib in combination with fulvestrant significantly increased progression-free survival compared with endocrine monotherapy in women with HR-positive, HER2-negative locally advanced or metastatic breast 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.
This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated by a physician experienced in the use of anticancer therapies. **FTEAM**

5.3. SMC 2636 - MOMELOTINIB (DISEASE-RELATED SPLENOMEGALY OR SYMPTOMS IN ADULTS WITH MODERATE TO SEVERE ANAEMIA WHO HAVE PRIMARY MYELOFIBROSIS, POST POLYCYTHAEMIA VERA MYELOFIBROSIS OR POST ESSENTIAL THROMBOCYTHAEMIA MYELOFIBROSIS)

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

The Group considered the request for momelotinib as an additional Janus Associated Kinase (JAK) inhibitor for the treatment of disease-related splenomegaly or symptoms in adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.

The Group noted that:

- myelofibrosis is a rare haematological disorder that often causes an enlarged spleen and constitutional symptoms (high symptom burden), and shortens life. The combined symptom burden can be very intense, and people can become dependent on carers.
- momelotinib is a JAK inhibitor, that was accepted for use in NHS Scotland following an abbreviated submission reviewed by the SMC executive
- other JAK inhibitors (ruxolitinib and fedratinib) are included on the formulary for the same patient group, ruxolitinib was accepted for use in NHS Scotland via the orphan medicine process
- local specialist are positioning momelotinib for use after ruxolitinib when resistance/intolerance or first-line if moderate/severe anaemia or baseline platelet count less than 50,000/mm^3
- evidence comes from two studies, MOMENTUM and SIMPLIFY-1

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- MOMENTUM provides data for the previously treated with JAK inhibitor population, with most data for intermediate-2 or high-risk myelofibrosis. All patients had received ruxolitinib and 3.6% of patients had also received fedratinib.
- SIMPLIFY-1 provides data for myelofibrosis patients who are JAK inhibitor naïve
- momelotinib showed lower rates of anaemia, and may be beneficial for adults who cannot use/continue ruxolitinib because of moderate to severe anaemia, or a platelet count less than 50,000/mm^3
- treatment with momelotinib would be continued for as long as the benefit-risk remains positive for patients, as assessed by the treating physician
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of momelotinib, PASs are also available for ruxolitinib and fedratinib
- some cost-offset is available, but use for adults with a platelet count less than 50,000/mm^3 would provide a new cost to the system

The Group accepted the restricted local need for momelotinib as an additional JAK inhibitor for the treatment of disease-related splenomegaly or symptoms in adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.

SMC 2636 - Momelotinib 100mg, 150mg, 200mg film-coated tablets (Omjjara®)▼ is routinely available in line with national guidance (SMC 2636).
Indication under review: treatment of disease-related splenomegaly or symptoms in adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are Janus Associated Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.
Momelotinib offers an additional treatment choice in the therapeutic class of JAK inhibitors in this setting.
Another medicine within this therapeutic class has been accepted via the orphan medicine process.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and monitored by physicians experienced in the use of anti-cancer medicinal products. **FTEAM**

5.4. NCMAG 111 - SUNITINIB (SECOND-LINE TREATMENT OF ADULTS WITH POOR OR INTERMEDIATE RISK ADVANCED/METASTATIC RENAL CELL CARCINOMA)

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

The Group considered the request for sunitinib as second-line treatment of poor or intermediate risk advanced/metastatic renal cell carcinoma in adults who have received nivolumab in combination with ipilimumab as first-line treatment.

The Group noted that:
- kidney cancer was the eighth most common cancer in Scotland. The risk of kidney cancer increases with age and most commonly occurs between 65 and 75 years of age.
- January 2024, NCMAG supported the use of sunitinib as a second-line treatment of poor or intermediate risk advanced/metastatic renal cell carcinoma in patients who have received nivolumab in combination with ipilimumab as first-line treatment
- sunitinib:
  - is a multi-targeted kinase inhibitor that works by inhibiting the growth of blood vessels around tumours, thus potentially shrinking and halting tumour growth
  - was initially licensed in 2006 as the reference product Sutent®, and is now available

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generically
  - is included on the formulary only for first-line use for the treatment of advanced/metastatic renal cell carcinoma in adults [NICE TA169]
- second-line treatment options depend on the previous treatment received
- patient numbers are expected to be very small, and treatment is continued until disease progression or unacceptable toxicity
- cost off-set is available as sunitinib would displace other second-line treatment options
- the service has experience prescribing and managing the adverse effects of sunitinib
- sunitinib is an oral treatment that patients can take at home, which will be beneficial for patients having previously attended hospital for regular infusions of nivolumab plus ipilimumab

The Group accepted the restricted local need for sunitinib as second-line treatment of poor or intermediate risk advanced/metastatic renal cell carcinoma in patients who have received nivolumab in combination with ipilimumab as first-line treatment.

NCMAG 111 - Sunitinib 12.5mg, 25mg hard capsules is routinely available in line with national guidance (NCMAG 111).
Indication under review: as second-line treatment of poor or intermediate risk advanced/metastatic renal cell carcinoma in adults who have received nivolumab in combination with ipilimumab as first-line treatment.
This advice applies only in the context of the confidential pricing agreements in NHS Scotland, upon which the decision was based, or confidential pricing agreements or 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. Therapy should be initiated by a physician experienced in the administration of anticancer agents. **FTEAM**

5.5. ADVANCED/METASTATIC RENAL CELL

5.5.1. SMC 2476 - LENVATINIB PLUS PEMBROLIZUMAB (FIRST-LINE ADVANCED/MRCC)

5.5.2. SMC 2386 - CABOZANTINIB PLUS NIVOLUMAB (FIRST-LINE ADVANCED/MRCC)

5.5.3. SMC 2199 - LENVATINIB PLUS EVEROLIMUS (ADVANCED/MRCC FOLLOWING ONE PRIOR VASCULAR ENDOTHELIAL GROWTH FACTOR (VEGF)-TARGETED THERAPY)

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

The Group considered requests for additional first- and second-line treatment regimens for the treatment of advanced and metastatic renal cell carcinoma (RCC).

The Group noted:
- the additional regimens were being requested to allow development of a renal Clinical Management Pathway
- all regimens are accepted for use in NHS Scotland by the SMC, and the SMC advice takes account of the benefits of PASs that improve the cost-effectiveness of treatment
- the budget impact is unlikely to be significant as there is significant cost-offset from the displacement of regimens currently included on the formulary
- the supplementary information from the European Society for Medical Oncology (ESMO) RCC clinical practice guidelines provides the ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS) table for therapies and indications in RCC
- sunitinib is the active comparator in the evidence for first-line regimens, with the requested regimens showing OS and PFS gains [over sunitinib]
- pembrolizumab plus lenvatinib is being requested on the basis of improved quality of life data
- in the second-line setting, treatment will depend on what people have received previously
- patients will not be re-challenged with an immune checkpoint inhibitor if they have

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	received it in the first-line setting	
	The Group accepted the restricted local need for additional first- and second-line treatment options for adults with advanced renal cell carcinoma to allow development of a renal Clinical Management Pathway.	
	SMC 2476 - Lenvatinib 4mg, 10mg hard capsules (Kisplyx®) is routinely available in line with national guidance (SMC 2476). **Indication under review: treatment of adults with advanced renal cell carcinoma (RCC), in combination with pembrolizumab, as first-line treatment.** **Restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.** **Lenvatinib offers an additional treatment choice in the therapeutic class of tyrosine kinase inhibitors given in combination with a PD-1/PD-L1 inhibitor for this indication.** **Medicines within this therapeutic class have been accepted under the end of life process for this indication.** **This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.** **Treatment should be initiated and supervised by a healthcare professional experienced in the use of anticancer therapies.**	**FTEAM**
	SMC 2386 - Cabozantinib 20mg, 40mg, 60mg film-coated tablets (Cabozantinib Ipsen) is routinely available in line with national guidance (SMC 2386). **Indication under review: in combination with nivolumab for the first-line treatment of advanced renal cell carcinoma in adults.** **Cabozantinib offers an additional treatment choice in the therapeutic class of tyrosine kinase inhibitors given in combination with a PD-1 inhibitor for this indication.** **Medicines within this therapeutic class have been accepted under the end of life process for this indication.** **This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.** **Therapy should be initiated by a physician experienced in the administration of anticancer medicinal products.**	**FTEAM**
	SMC 2199 – Lenvatinib 4mg, 10mg hard capsules (Kisplyx®) is routinely available in line with national guidance (SMC 2199). **Indication under review: in combination with everolimus for the treatment of adults with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy.** **In a phase II study, the addition of lenvatinib to everolimus significantly improved progression-free survival in patients with advanced renal cell carcinoma who had received one previous VEGF-targeted therapy.** **This advice applies only in the context of an 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.** **This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.**	

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	Treatment should be initiated and supervised by a healthcare professional experienced in the use of anticancer therapies.	**FTEAM**

6. FORMULARY REVIEW

6.1. FORMULARY UPDATES NOVEMBER 2024

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

The Group reviewed the Formulary Team's summary document highlighting a change in formulary wording for an ultra-orphan medicine, name changes for two formulary medicines and some discontinued medicines.

ULTRA-ORPHAN MEDICINES ASSESSMENT REPORT

Ms Doney confirmed that:

- SMC 2561 is an ultra-orphan medicines assessment report (UMAR). Medicines undergoing an initial assessment of evidence by the SMC are considered outwith remit for the Formulary Group; these medicines will ultimately be accessed via the Scottish Government ultra-orphan pathway.
- July 2024, using the ultra-orphan framework, the SMC completed its initial assessment of the evidence for Filsuvez® gel as a treatment of partial thickness wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in patients 6 months and older.
- August 2024 Filsuvez® gel was added to the formulary as '*Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist – Supply (ARI).*'
- the Scottish Government confirmed that from 30 October 2024, birch bark extract gel (Filsuvez®) can be prescribed within the ultra-orphan pathway while further evidence on its effectiveness is generated. After 3 years the company will provide an updated submission for reassessment to allow a decision on its routine use in NHS Scotland.

The Group supported updating formulary decision wording to 'Not routinely available in NHS Grampian. *If local need identified treatment is available through the National Services Scotland Ultra orphan medicines Risk Share Scheme'*. **FTEAM**

NAME CHANGES

Ms Doney confirmed that:

- baricitinib tablets, previously branded as Olumiant®, are now baricitinib Lilly (2mg, 4mg) tablets
- mirabegron tablets, previously branded as Betmiga®, are now mirabegron Astellas (25mg, 50mg) prolonged release tablets
- only the name and packaging of the drugs have changed, the previous PAS agreements, formulary decisions/positioning remain the same

The Group supported updating the current formulary entries to remove the brand names and add as the generic names only. The proposed name change will be highlighted to the local and regional HEPMA Teams. **FTEAM**

DISCONTINUATIONS

The Group supported the Formulary Team's suggested action to amend the formulary entries to note that the product is withdrawn from use/discontinued for:

- Kay-Cee-L® 375mg/5mL syrup (potassium chloride). Discontinued after long term supply issues, alternative licensed product available on the formulary.

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- Komboglyze® 2.5mg/1g tablets (saxagliptin/metformin). Currently non-formulary, other products preferred.
- NovoRapid® FlexTouch 100units/mL (insulin aspart). This medicine is available in alternative pens/device.

Ms Doney confirmed that:
- the MAH confirmed that liraglutide as the brand Victoza®, licensed for Type 2 diabetes mellitus, has been discontinued after a long period of out of stock
- multiple suppliers are expected to launch biosimilar equivalents following patent expiry on 26th November 2024
- it is not known if the biosimilar products will only be licensed for diabetes, or will also be licensed for weight management

The Group supported removing the brand name from the current formulary entry and noting the withdrawal of Victoza® 6mg/mL solution for injection in pre-filled pen (liraglutide). **FTEAM**

6.2. FORMULARY REPORTING

6.2.1. CMO REPORT FOR APRIL 2024 TO OCTOBER 2024 DECISIONS

6.2.2. 93 DAY REPORT FOR FORMULARY DECISIONS APRIL 2024 TO OCTOBER 2024

6.2.3. NCMAG REPORT FOR APRIL 2024 TO OCTOBER 2024

Members noted the reports for April to October 2024.

Ms Doney confirmed that an error was published on the August 2024 decisions document. The advice for pembrolizumab SMC 2664 was recorded as 'routinely available' rather than 'not recommended for use in NHS Scotland'.
The document will be corrected and re-issued. **FTEAM**

7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED OCTOBER 2024

The Group noted the SMC advice published November 2024.

Following publication of the negative SMC recommendation for pembrolizumab (Keytruda®) SMC 2688, and the non-submission statement for enzalutamide (Xtandi®) SMC 2742, 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 2707 lebrikizumab (Ebglyss®)▼ (submission expected)
- SMC 2631 linzagolix (Yselty®)▼
- SMC 2699 quizartinib (Vanflyta®)▼
- SMC 2701 Pylera® (bismuth subcitrate potassium/metronidazole/tetracycline) (submission expected)
- SMC 2629 somapacitan (Sogroya®)▼
- SMC 2697 tenecteplase (Metalyse®) (submission expected)

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

ITEM	SUBJECT	ACTION

7.2. SMC 2695 - YESCARTA® (DLBCL)

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

Members noted that:

- at the August 2024 meeting, it was agreed that SMC accepted CAR (chimeric antigen receptor) T-cell therapy indications would be included on the formulary without the need for full submissions
- SMC 2695 is a resubmission, assessed under the end of life and orphan medicine process
- National Service Division funding is in place for CAR-T cell therapies

The Group accepted the restricted local need for axicabtagene ciloleucel 0.4 – 2 x 10^8 cells dispersion for infusion for the treatment of adults with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) that relapses within 12 months from completion of, or is refractory to, first-line chemo-immunotherapy, as outlined in SMC 2695.

SMC 2695 - Axicabtagene ciloleucel 0.4 – 2 x 10^8 cells dispersion for infusion (Yescarta®)▼ is routinely available in line with national guidance (SMC 2695).
Indication: for the treatment of adults with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy.
In a randomised, open-label, phase III study in patients with relapsed or refractory DLBCL or HGBL, axicabtagene ciloleucel significantly improved event-free survival compared with standard of care.
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.
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**

7.3. NCMAG ADVICE PUBLISHED OCTOBER 2024

The Group noted the NCMAG advice published October 2024.

The following NCMAG supported medicines have not been processed within a 60-day timescale:

- NCMAG 113 anastrazole
- NCMAG 114 raloxifene
- NCMAG 115 tamoxifen
- NCMAG 118 trametinib (Mekinist®)

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

ITEM	SUBJECT	ACTION

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED NOVEMBER 2024

The Group noted the SMC provisional advice issued November 2024.

If the negative SMC recommendations are published next month, these medicines will not be included on the formulary for the indications in question.

9. OTHER BUSINESS

9.1. LETTER TO BOARD MEDICAL DIRECTORS - INFECTED BLOOD INQUIRY RECOMMENDATIONS FOR HEALTH BOARDS RELATING TO CLINICAL BLOOD TRANSFUSION PRACTICE AND PATIENT BLOOD MANAGEMENT

The letter to the Medical Directors was noted.

10. DOCUMENTS FOR INFORMATION

Items 10.1 (Drug Safety Update October 2024), 10.2 (Acute and Mental Health Medicines Safety Group meeting minute August 2024), 10.3 (Medicines Guidelines and Policies Group meeting minute May 2024), 10.4 (Grampian Area Drug and Therapeutics Committee meeting minute May 2024), 10.5 (Antimicrobial Management Team meeting minute August 2024) and 10.6 (MedWatch newsletter November 2024) were noted.

11. AOCB

None.

DATE OF NEXT MEETING

Tuesday 21 January 2025 starting at 14.30 via Microsoft Teams

Signature on file

CHAIR'S SIGNATURE **Fiona Doney** **DATE 18 FEBRUARY 2025**