NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 17 January 2023 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Miss R Anderson	Ms A Davie	
Ms L Cameron	Dr E Elias	
Dr V Chieng	Mrs K Neave	
Dr D Culligan		
Ms F Doney (Vice-Chair)		
Dr L Elliot (Chair)		
Ms M Galvin		
Mrs G McKerron		
Dr M Metcalfe (Vice-Chair, from item 4.3)		
Dr J Newmark (from item 8.2)		
Mr M Paterson		
Mr R Sivewright		

IN ATTENDANCE
Mrs Sarah Howlett, Haematology pharmacist, (observer).

ITEM	SUBJECT	ACTION

WELCOME

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

The Chair welcomed Miss Rebecca Anderson to the Group as the Medicines Information representative while Mrs O'Beirne is off.

Mrs Sarah Howlett, Haematology Pharmacist, was introduced to the Group. Mrs Howlett is an observer for this meeting but joining the Group, as the Acute Pharmacy representative, from the February meeting to cover while Ms Galvin is off.

The Chair confirmed that Ms Galvin was going off on maternity leave soon and this would be her last meeting for a while. The Chair thanked Ms Galvin for all of the work she has done for the Group, and members wished her well for the future.

1. APOLOGIES

Apologies for absence were requested and noted.

2. DRAFT MINUTE OF THE MEETING HELD 20 DECEMBER 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 final approval. **FD**

3. PRESENTATION

None.

4. MATTERS ARISING

4.1. ACTION LOG

The action log was noted.
No additional items were identified for discussion at the meeting.

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4.2. FARICIMAB (UPDATE)

Ms Doney reported that, shortly after the December meeting, the licence for faricimab was updated to include a 'treat and extend' regimen. The adverse drug reactions were updated following release of additional data.

4.3. CRIZANLIZUMAB (FOR INFORMATION)

Ms Doney reported that the requestor answered the Formulary Team's review queries for crizanlizumab.

It was confirmed that:
- the decision to prescribe crizanlizumab will be agreed at a national multi-disciplinary team meeting
- there will be no time restriction on prescription, stopping treatment will be dictated by patient response (or lack thereof)
- patients on regular transfusions will not be offered crizanlizumab, however it would be an alternative to transfusion, not an adjunct

Item closed. **FTEAM**

5. FORMULARY GROUP DECISIONS DECEMBER 2022 - PUBLISHED 30/12/2022

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

6. NETFORMULARY/FORMULARY REVIEW

6.1. MONOAMINE-OXIDASE B INHIBITORS ON FORMULARY

The Group discussed the formulary inclusion request prepared by the Formulary Team for rasagiline as an alternative monoamine-oxidase B (MOA-B) inhibitor used for Parkinson's disease.

Ms Doney confirmed that there is a shortage of the MOA-B inhibitor selegiline, and the alternative agent rasagiline is not currently noted as a formulary medicine. Formulary inclusion of rasagiline would have formed part of the formulary section review for Parkinson's disease. However to minimise issues with the current selegiline shortage, the request for formulary inclusion was brought forward.

The Group noted that:
- when first marketed rasagiline, as the reference product Azilect®, was not recommended for use in NHS Scotland on economic grounds (at that time it was ~10 times more expensive than selegiline, SMC 243/06 and SMC 255/06)
- the availability of generic rasagiline has reduced costs significantly, with rasagiline now costing less than selegiline, and the SMC advice should not be considered extant
- both rasagiline and selegiline are included in the Scottish Drug Tariff (SDT), however, there is currently only one manufacturer for selegiline, with several companies for rasagiline
- there is a lack of head-to-head data comparing the MAO-B inhibitors, however a 2017 Drug and Therapeutics Bulletin (DTB) Select article suggests that given the absence of a significant major difference in outcome between the drugs, a sensible first-line choice would be the drug with the lowest acquisition cost
- at current costs rasagiline, prescribed generically, has the lowest acquisition cost

The Group accepted the restricted local need for rasagiline tablets, as licensed, without the need for a full submission.

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	SBAR - Rasagiline 1mg tablets is routinely available in line with local guidance. Indication under review: for the treatment of idiopathic Parkinson's disease as monotherapy (without levodopa) or as adjunct therapy (with levodopa) in adults with end of dose fluctuations **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**

7. OTHER BUSINESS

7.1. GOVERNANCE AND PROCESSES

Ms Doney reported that a review of the Group's Terms of reference, processes, and classification system is underway, with review and sign off by the Group required by the end of March.

7.2. DECLARATION OF INTEREST REGISTER 2022

Ms Doney reported that the Group's Register of Interests for 2022 must be closed off by the end of March.
Emails will be sent in the next few weeks asking members to confirm their declarations for the calendar year 2022. New members are required to provide a declaration for 2022. **ALL**

8. NEW PRODUCT REQUESTS

8.1. SMC 2493 - SOMATROGON (GROWTH DISTURBANCE DUE TO GROWTH HORMONE DEFICIENCY)

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

The Group considered the request for somatrogon for the treatment of children and adolescents with growth disturbance due to insufficient secretion of growth hormone.

The Group noted:

- August 2022, following review by the SMC executive, SMC published an abbreviated submission accepting somatrogon (Ngenla®) for use within NHS Scotland, for the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone [SMC 2493]
- somatrogon:
  - has an orphan designation from the Medicines and Healthcare products Regulatory Agency (MHRA)
  - is a version of natural human growth hormone which has been modified by combining it with part of another human hormone. As only a part of the other hormone is used, it does not have an effect on the body, but the combination allows somatrogon to remain active in the body for a longer time than natural growth hormone so injections do not need to be given daily.
- the alternative somatropin, is available on the formulary as various brands and devices, must be given/taken by subcutaneous injection daily
- there is currently a shortage of one of the preferred somatropin preparations
- national guidance on the use of growth hormone is available from NICE and the Scottish Paediatric Endocrine Group (SPEG) National Managed Clinical Network
- evidence of efficacy and safety [of somatrogon for the treatment of children and adolescents from 3 years of age with growth hormone deficiency (GHD)] were evaluated in two multi-centre randomised, open-label controlled clinical studies:
  - both studies included a 12-month main study period (0.66mg/kg/week) that compared once-weekly somatrogon to somatropin administered once-daily (0.034mg/kg/day) followed by a single-arm open-label extension period during which all patients were administered somatrogon once-weekly

  - the primary efficacy endpoint was annualised height velocity (HV) following 12 months of treatment
  - in the pivotal study (CP-4-006 +OLE; n = 224) once-weekly somatrogon was non-inferior based on HV at 12 months compared to somatropin administered once daily. The average rate of growth over a year was 10.1cm versus 9.8cm for those given somatropin. Other measures of growth, such as bone maturation, were also comparable between children from both groups.
- following multiple weekly administrations of somatrogon, no relevant accumulation of somatrogon is expected in children with GHD
- somatrogon injection is available in 1.2mL pre-filled pens containing 24mg (20mg/mL) and 60mg (50mg/mL), that at list price cost £166.08 and £415.20 (ex VAT) respectively (both equivalent to £6.92/mg)
- each pen has an in-use shelf-life of up to 28 days after first use, and should be discarded if it has been used 5 times. To minimise waste doses below 12mg weekly, i.e., patients weighing less than 18kg, should be given using the 24mg pen.
- somatrogon injection is licensed for children and adolescents but national guidance notes that in some cases growth hormone can be given to adults, e.g., up to 25 years
- cost-offset is available from the displacement of somatropin, and significantly fewer needles will be used for weekly injections compared with daily injections
- regular monitoring will be required, but this potentially represents disease-monitoring rather than drug monitoring
- availability of a weekly injection would be particularly useful for those with poor compliance with a daily injection

Members discussed the formulary request and potential to transfer prescribing to Primary Care. Members considered that care of this patient group is a highly specialist area, and treatment should be initiated and monitored by physicians who are qualified and experienced in the diagnosis and management of paediatric patients with GHD.
Primary Care colleagues would not be involved in the counselling, dosage instruction or monitoring/interpretation of results, and members were unsure if the insulin-like growth factor-1 (IGF-1) test was available in Primary Care.
With the small numbers, there was a concern about how familiar General Practice would become with the drug, and the risk of errors with prescribing.

Due to the small number of patients, the highly specialist nature of disease management, and concerns with dose changes/prescribing in Primary Care, members requested further information to support decision-making.

Queries:
- how often do children/adolescents with GHD attend clinic?
- who is responsible for monitoring and recommending dosage changes, and how is this information shared with patients/carers and practices? Including device changes.
- is IGF-1 testing available in primary care?
- do patients/carers have access to specialist nurses via phone line and/or email?
- do the specialist nurses provide training (for devices etc.) to patients/carers in the specialist clinic in acute or community, or both?

The Group was minded to accept somatrogon to formulary, but considered that additional information was needed to support decision-making and to clarify the formulary classification. The Group deferred decision-making to a future meeting. **FTEAM**

SMC 2493 - Somatrogon 24mg, 60mg solution for injection in pre-filled pen (Ngenla®) ▼ decision deferred to future meeting.
Indication under review: for the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone.
Somatrogon offers an additional treatment choice in the therapeutic class of

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	recommendant human growth hormones for this indication. **Decision deferred to future meeting.**	**FTEAM**

8.2. SMC 2447 - DARATUMUMAB (AL AMYLOIDOSIS)

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

The Group considered the request for daratumumab subcutaneous (s/c) injection for the treatment of adults with newly diagnosed systemic light chain (AL) amyloidosis.

The Group noted that:

- AL amyloidosis:
  - is a rare complex disease, and diagnosis can be hard, as the symptoms are often vague
  - can be difficult to treat and patients present late with significant frailty
  - has a high symptom burden and the build-up of amyloid deposits can cause progressive organ dysfunction affecting kidneys, heart and nerves
- daratumumab:
  - [for this indication] was accepted for use in NHS Scotland following a full submission assessed under the orphan medicine process, the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
  - [for this indication] is given in combination with cyclophosphamide, bortezomib and dexamethasone (VCd)
- there are currently no licensed treatment options for AL amyloidosis. Standard therapies are based on the treatment of multiple myeloma, used off-label, e.g., combination therapy with VCd
- evidence comes from ANDROMEDA an open-label, randomised, active-controlled phase III study which evaluated daratumumab s/c in combination with VCd (D-VCd; n = 195) compared with VCd alone (n = 195) in patients with newly diagnosed systemic AL amyloidosis
- ANDROMEDA:
  - six 28-day cycles of D-VCd or weekly VCd. Patients in the D-VCd arm received daratumumab monotherapy after cycle 6 every 4 weeks up to a total of 24 cycles (~2 years) from the first dose.
  - the primary end point was hematologic complete response rate; secondary end points included major organ deterioration-progression-free survival, organ response rate, time to hematologic response, overall survival, and safety
  - at a median follow-up of 25.8 months, patients who received D-VCd achieved a significantly higher rate of hematologic complete response than those in the VCd arm (59.5% vs 19.2%, respectively; odds ratio, 6.03; P <.0001). More patients in the D-VCd group achieved a very good partial response or better (79.0% vs 50.3%, respectively; odds ratio, 3.74; P <.0001) compared with the VCd arm.
- updated result of the ANDROMEDA study (18-month longer follow-up):
  - demonstrated the sustained clinical benefits of D-VCd versus VCd in terms of hematologic and organ responses - the D-VCd treatment arm showed higher rates of deep hematologic responses and organ responses
  - showed the median duration of treatment for daratumumab was 21.3 months
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of daratumumab injection
- patient numbers are expected to be small, and patients are managed in conjunction with the National Amyloidosis Centre
- daratumumab [for this indication] would be a new [medicine] cost to the service. Costs may already be in the system as newly diagnosed patients would have received treatment on the recommendation of the National Amyloidosis Centre via the individual treatment request process.

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The Group accepted the restricted local need for daratumumab injection for the treatment of adults with newly diagnosed systemic AL amyloidosis, as outlined in SMC 2447.

SMC 2447 - Daratumumab 1,800mg solution for injection (Darzalex®) is routinely available in line with national guidance (SMC 2447).
Indication under review: in combination with cyclophosphamide, bortezomib and dexamethasone for the treatment of adults with newly diagnosed systemic light chain (AL) amyloidosis.
In a phase III study in patients with newly diagnosed AL amyloidosis with at least one affected organ, the addition of daratumumab to bortezomib, cyclophosphamide and dexamethasone was associated with a significant improvement in complete haematologic response rate.
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.
Daratumumab subcutaneous formulation is not intended for intravenous administration and should be given by subcutaneous injection only, using the doses specified. Treatment should be administered by a healthcare professional, and the first dose should be administered in an environment where resuscitation facilities are available. **FTEAM**

8.3. SMC 2430 - OPICAPONE (PARKINSON'S DISEASE)

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

The Group considered the request to include the catechol-*O*-methyltransferase (COMT) inhibitor opicapone on the formulary.

The Group noted that:

- January 2022, following an abbreviated submission reviewed by the SMC executive, opicapone was accepted for use within NHS Scotland, as licensed, as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCI) in adults with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations (SMC 2430)
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of opicapone
- efficacy and safety comes from two pivotal randomised, double-blind, phase III studies, BIPARK-I (n=590) and BIPARK II (n=411). The studies recruited levodopa-treated patients with idiopathic Parkinson's disease and motor fluctuations. The primary end point of both studies was an absolute reduction in OFF-time.
- BIPARK I:
  - patients were randomly assigned opicapone 5mg, 25mg or 50mg, entacapone or placebo (n = 590, 115 in the opicapone 50mg group).
  - treatment with opicapone 50mg was superior to placebo (mean difference in change from baseline –60·8 min, 95% CI –97·2 to –24·4; p=0·0015) and non-inferior to entacapone (–26·2 min, –63·8 to 11·4; p=0·0051)
  - treatment with opicapone 5mg (p=0·056) or 25mg (p=0·080) was not significantly different from treatment with placebo
  - patients receiving opicapone 50mg achieved a mean change of ~ 60 minutes reduction in OFF-time compared to placebo (– 60.8 minutes). Whereas, entacapone treatment vs. placebo achieved a mean change of – 40.3 minutes.
- BIPARK-II:
  - 25mg and 50mg of opicapone, administered once-daily, compared with placebo,

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administered with each dose of levodopa. Patients' inclusion criteria and trial assessments (primary and secondary outcomes) were similar to BIPARK-I.
    - mean reduction in absolute OFF-time in both the 25mg and 50mg opicapone groups was greater than in the placebo arm (1.7, 2.0 and 1.1 h, respectively). The 50mg opicapone was significantly better than placebo (p=0.0084).
- study limitations:
    - limited data is available in patients treated with controlled-release formulations of levodopa. There is no evidence that either the efficacy or safety of opicapone would be affected by use of controlled-release levodopa preparations, however, experience with such preparations is limited.
    - short-term studies for potentially medium to long-term treatment option. However, extension studies (of 1 year, n = 862) indicated maintenance of the effect achieved during double-blind study periods.
- the Service confirmed that opicapone will be used as an alternative to entacapone, where the patient has already tried an MAO-B inhibitor and either entacapone is not tolerated or there is insufficient benefit from entacapone
- there will be a degree of cost-offset available from the displacement of entacapone, with the potential for a lower pill burden

The Group accepted the restricted local need for opicapone, as an additional COMT inhibitor, available for use after failure of entacapone, or in patients who cannot tolerate entacapone.

SMC 2430 - Opicapone 50mg hard capsules (Ongentys®) is routinely available in line with local guidance.
Indication under review: as adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCI) in adults with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations.
Restriction: used after failure of entacapone, or in patients who cannot tolerate entacapone.
Opicapone provides an additional treatment choice in the therapeutic class of catechol-O-methyl transferase inhibitors.
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 8d - treatment may be initiated in community on the recommendation of a consultant/specialist. **FTEAM**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE ISSUED JANUARY 2023

The Group noted the SMC provisional advice issued January 2023.

10. ADVICE PUBLISHED JANUARY 2023

10.1. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS PUBLISHED JANUARY 2023

The Group noted the SMC advice published January 2023.

Following publication of the negative SMC recommendation, for ferric maltol (Feraccru®) SMC 2500, and the non-submission statements, for Drovelis® ▼ (drospirenone/estetrol monohydrate) SMC 2564, setmelanotide (Imcivree®) ▼ SMC 2565 and tisagenlecleucel (Kymriah®) ▼ SMC 2566, 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:

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- SMC 2516 - mobocertinib (Exkivity®) ▼ (clinicians not responded)
- SMC 2535 - tepotinib (Tepmetko®) ▼ (clinicians not responded)

Local advice for these medicines and indications will be included in the January 2023 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

10.2. NATIONAL CANCER MEDICINES ADVISORY GROUP ADVICE PUBLISHED JANUARY 2023

The Group noted the NCMAG advice published January 2023.

The following NCMAG advice has not been processed within a 60-day timescale:

- NCMAG 102 - abiraterone acetate (planned for discussion at the February Formulary Group meeting)

Local advice for this medicine and indication will be included in the January 2023 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

The Group considered the advice published by the National Cancer Medicines Advisory Group (NCMAG) for the off-label use of carfilzomib and trastuzumab.

10.2.1. NCMAG 104 - CARFILZOMIB (OFF-LABEL ONCE-WEEKLY DOSING REGIMEN)

Ms Galvin declared a personal, non-specific interest in Amgen Limited and took part in the discussion and decision-making.

The Group considered the NCMAG advice supporting the off-label use of a once-weekly carfilzomib (in combination with dexamethasone) regimen for the treatment of adults with multiple myeloma who have received at least one prior therapy.

The Group noted that:

- multiple myeloma is an incurable haematological cancer that causes the destruction of bone and bone marrow leading to bone fractures, anaemia, low platelets, susceptibility to infections, high calcium levels in the blood and kidney dysfunction.
- relapsed myeloma can have significant symptom burden including pain. Improvements in quality of life in the relapsed setting are less than those achieved with first-line treatment.
- carfilzomib (in combination with dexamethasone alone) is routinely available in NHS Scotland for the treatment of adults with multiple myeloma who have received at least one prior treatment, SMC 1242/17
- there is a lack of direct evidence comparing off-label carfilzomib 70mg/m^2 body surface area (BSA) once-weekly with the licensed 56mg/m^2 BSA twice-weekly regimen. However, post-hoc side-by-side analysis from three studies suggested a similar objective response rate (ORR, 70% versus 72%) and progression free survival (PFS, 12 months compared to 14 months). Following adjustment for prognostic covariates there was no evidence of a difference between the regimens for ORR (OR 1.12, 95% CI 0.74-1.69) and PFS (HR 0.91; 95% CI 0.69-1.19).
- greater health-related quality of life (HRQOL) was noted in the once-weekly compared to the twice-weekly regimen for the physical functioning, role functioning and fatigue. There was a trend towards greater satisfaction and convenience for patients who received the once-weekly regimen compared with the twice-weekly regimen.
- the NCMAG advice takes account of the benefits of a PAS that improves the cost-effectiveness of carfilzomib
- medicine costs will reduce, but the service impact is halved - 50% reduction in day case unit chair time for chemotherapy IV administration, nursing time, pharmacy aseptic service compounding. The cost changes are already in the system as the

Haematology service moved to this regimen during COVID, when this treatment was available under interim NCMAG advice.
- there are no direct cost-effectiveness data, but NCMAG conducted a cost-minimisation analysis that provided suitably robust results

Ms Galvin confirmed that during COVID the once-weekly regimen was well received by patients, particularly those receiving carfilzomib as a later line of treatment, e.g., fourth-line. The Service is keen to have the once-weekly regimen included on the formulary as an option for patients.

The Group accepted the restricted local need for the off-label use of carfilzomib in line with NCMAG 104, without the need for a full submission. The off-label once-weekly carfilzomib regimen will provide an alternative option to the licensed twice-weekly regimen.

NCMAG 104 - Carfilzomib 10mg, 30mg, 60mg powder for solution for infusion (Kyprolis®) is routinely available in line with national guidance (NCMAG 104).
Indication under review: [off-label use] once-weekly regimen in combination with dexamethasone alone for the treatment of adults with multiple myeloma who have received at least one prior therapy.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement, or the national framework contract price, delivering the cost-effectiveness results upon which the decision was based, or a PAS/ national framework contract/ list price that is equivalent or lower.
It was classified 3b - licensed product requested for unlicensed use and 8b - recommended for hospital use only.
Informed consent should be obtained and documented. Treatment should be supervised by a physician experienced in the use of anti-cancer therapy. **FTEAM**

10.2.2. NCMAG 105 - TRASTUZUMAB (OFF-LABEL REDUCED TREATMENT DURATION)

Dr Culligan declared a personal, non-specific interest in Roche Products Limited and took part in decision-making.
Ms Galvin previously declared a personal, non-specific interest in Amgen Limited and took part in the discussion and decision-making.

The Group considered the NCMAG advice supporting an off-label 6-month treatment duration of trastuzumab for the treatment of adults with human epidermal growth factor receptor 2 (HER2) positive early breast cancer.

The Group noted that:
- in patients with early breast cancer who are suitable for trastuzumab, one year of treatment has been the standard of care
- there is published evidence comparing the 6-month regimen with a 12-month treatment duration of trastuzumab
- following the publication of recent studies comparing 12 months with 6 months duration, the European Society of Medical Oncology (ESMO) recommends consideration of six months trastuzumab as a treatment option for highly selected patients
- there is no published analysis focused on the proposed low-risk patient group
- trastuzumab IV and Herceptin® S/C are subject to confidential pricing arrangements
- use of a shorter treatment duration will have a lower service impact - reduced patient visits for clinic appointments and administration, reduced cardiac monitoring using echocardiogram, and reduced costs related to the management of adverse events
- a published cost-utility analysis is available that provided suitably robust results
- six months of trastuzumab offers a shorter treatment duration for patients, and has a lower rate of significant adverse effects compared to 12 months of treatment. Use of

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the 6-month regimen may be most appropriate in the patient group with lower clinical pathological risk and lower absolute benefit from treatment.

Ms Galvin confirmed that the off-label treatment regimen will be included in the national clinical treatment pathway for breast cancer, and inclusion on formulary will provide an alternative option for some patients.

The Group accepted the restricted local need for the off-label reduced treatment duration of trastuzumab in the neoadjuvant and adjuvant settings for patients with HER2 positive early breast cancer categorised as low risk. The off-label 6-month trastuzumab regimen will provide an alternative option to the licensed 12-month regimen.

NCMAG 105 - Trastuzumab 150mg, 420mg powder for concentrate for solution for infusion is routinely available in line with national guidance (NCMAG 105).
Indication under review: [off-label use] reduced treatment duration of 6-months in the neoadjuvant and adjuvant treatment pathways, for adults categorised as lower risk with human epidermal growth factor receptor 2 (HER2) positive early breast cancer (EBC).
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement, or the national framework contract price, delivering the cost-effectiveness results upon which the decision was based, or a PAS/ national framework contract/ list price that is equivalent or lower.
It was classified 3b - licensed product requested for unlicensed use and 8b - recommended for hospital use only. Informed consent should be obtained and documented.
HER2 testing is mandatory prior to initiation of therapy. Treatment should only be initiated by a physician experienced in the administration of cytotoxic chemotherapy, and should be administered by a healthcare professional only.
In order to prevent medication errors it is important to check the vial labels to ensure that the medicinal product being prepared and administered is trastuzumab intravenous infusion and not another trastuzumab-containing product (e.g. trastuzumab emtansine or trastuzumab deruxtecan or Herceptin® 600mg solution for injection). **FTEAM**

NCMAG 105 - Trastuzumab 600mg solution for subcutaneous injection (Herceptin®) is routinely available in line with national guidance (NCMAG 105).
Indication under review: [off-label use] reduced treatment duration of 6-months in the neoadjuvant and adjuvant treatment pathways, for adults categorised as lower risk with human epidermal growth factor receptor 2 (HER2) positive early breast cancer (EBC).
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement, or the national framework contract price, delivering the cost-effectiveness results upon which the decision was based, or a PAS/ national framework contract/ list price that is equivalent or lower.
It was classified 3b - licensed product requested for unlicensed use and 8b - recommended for hospital use only. Informed consent should be obtained and documented.
HER2 testing is mandatory prior to initiation of therapy. Treatment should only be initiated by a physician experienced in the administration of cytotoxic chemotherapy, and should be administered by a healthcare professional only.
Herceptin® subcutaneous formulation is not intended for intravenous administration and should be administered via a subcutaneous injection only.
In order to prevent medication errors it is important to check the vial labels to ensure that the drug being prepared and administered is Herceptin® (trastuzumab) and not another trastuzumab-containing product (e.g., trastuzumab emtansine or trastuzumab deruxtecan). **FTEAM**

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11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM - JANUARY 2023

None.

12. DOCUMENTS FOR INFORMATION

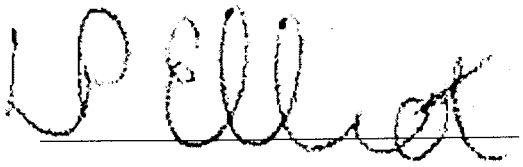
Item 12.1 (Primary Care Prescribing Group minute September 2022) was noted.

13. AOCB

None.

DATE OF NEXT MEETING

Tuesday 21 February 2023 starting at 14.30 via Microsoft Teams

CHAIR'S SIGNATURE  **DATE 21 FEBRUARY 2023**