NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 19 March 2019 at 14:30 in the Seminar Room, David Anderson Building

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Dr J Fitton	
Ms F Doney	Mrs L Harper	
Dr L Elliot	Dr A MacDonald	
Ms M Galvin (from item 6.1)	Mrs L Montgomery	
Professor J McLay (Chairman)	Dr W Moore	
Mr M Paterson	Dr A Sun	
Mr C Rore		
Mr R Sivewright		

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The Chairman welcomed members, opened the meeting and noted that a quorum was not present.

It was reported that due to a clash of meetings Ms Galvin would be late and that the meeting would be quorate if she attends the meeting.

The Chairman confirmed that the meeting would go ahead but any decisions made would not be valid until the meeting was quorate. Any decisions reached would be ratified when quorum was reached or at a future quorate meeting.

1. APOLOGIES

Apologies for absence were requested and noted.

2. DRAFT MINUTE OF THE MEETING HELD 19 FEBRUARY 2019

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

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

3. PRESENTATION - NONE

4. MATTERS ARISING

4.1. ACTION LOG

4.1.1. HYDROCHLOROTHIAZIDE DRUG SAFETY

Ms Doney confirmed that the hydrochlorothiazide letter would be issued after the meeting. **FTeam**

ITEMS NOT ON THE AGENDA

PRESCRIBING RESTRICTIONS FOR FLUOROQUINOLONE AND QUINOLONE ANTIBIOTICS
Ms Doney confirmed that in February the Antimicrobial Management Team issued an SBAR outlining the recommended restrictions to the use of fluoroquinolone antibiotics. The SBAR was issued to the Acute service and the Antibiotic Pharmacists will arrange for it to be issued to Primary Care.

This item will be removed from the Action log. **FTeam**

PRIMARY CARE REBATE – DECAPEPTYL® INJECTION
Ms Doney confirmed that she has received personal communication that the confidential Primary Care discount for Decapeptyl® injection has been extended. Members agreed to close this item and further information will only come back to Group if the discount is reduced or withdrawn.

This item will be removed from the Action log. **FD**

LIPID GUIDANCE
Ms Davie requested an update regarding the lipid guidance. Ms Doney reported that cost comparison charts for the oral lipid-lowering therapies have been created and shared with

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the specialist service, but she was unsure if the guidance is available on the intranet.

The Formulary Team will check if guidance is available on the intranet. **FTeam**

5. FORMULARY GROUP DECISIONS FEBRUARY 2019 - PUBLISHED 05/03/2019

5.1. FORMULARY GROUP DECISIONS FEBRUARY 2019

Members ratified the decisions of the February 2019 meeting as published.

5.2. DRAFT NETFORMULARY UPDATE FOR JANUARY 2019 FORMULARY GROUP DECISIONS AND

5.3. PROPOSAL FOR PUBLICATION OF DECISIONS

Ms Doney confirmed that due to workload pressures, the netFormulary update and proposal for publication of decisions were not available for the meeting.

The draft proposal:
- seeks to formalise the publication process and provide members with the necessary assurance that any governance concerns are addressed
- requests delegated authority to publish decisions
- uses existing processes and documentation to report compliance with agreed timescales, and exception reporting when these timescales are not met
- considers if an executive committee is needed to authorise formulary entries where the situation is not 'standard' or would benefit from further scrutiny

The proposal is drafted and will be issued to members for review at the next meeting. **FTeam**

6. NETFORMULARY/FORMULARY REVIEW

6.1. LONG-ACTING REVERSIBLE CONTRACEPTION

There were no declarations of interest recorded in relation to Gedeon Richter (UK) Ltd or OCON Medical Ltd.

Members considered the Formulary Team's review of long-acting reversible contraception/contraceptives (LARC).

Members noted:
- there are four levonorgestrel-containing intrauterine devices/systems (LNG-IUS), and all are licensed for contraception
- Mirena® is the only LNG-IUS that is licensed for protection from endometrial hyperplasia during oestrogen replacement therapy
- the licensing of Levosert®, for both heavy menstrual bleeding and contraception, has increased from 4 to 5 years [which, for these indications, is the same as the licensing for Mirena®]
- the Levosert® inserter is different to those used for the other LNG-IUSs, however it is very similar to those used for copper intrauterine devices (Cu-IUDs, e.g. Nova-T® and UT380)
- the managed service benefits from confidential contract prices for some LNG-IUSs
- if Levosert® is accepted to formulary the local enhanced service contract for intra-uterine contraception may need to be reviewed

Members discussed the differences between the devices, insertion process, and the risk of a failed insertion in Primary Care, including the potential for a significant negative perception about the insertion/use of LARCs.
Taking all of the points into consideration the Group supported the restricted local need for Levosert®, noting that use in Primary Care would benefit from planned introduction.

Ms Doney will check if the local enhanced service contract requires updating to include Levosert®. **FD**

SMC 1058/15 - Levosert® 20 micrograms/24 hours intrauterine delivery system (IUS) is routinely available in line with local guidance.
Indications under review:

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- **contraception**
- **treatment of heavy menstrual bleeding. Levosert® may be particularly useful in women with heavy menstrual bleeding requiring (reversible) contraception.**

Levosert® should only be inserted by physicians/health care professionals who are experienced in levonorgestrel IUS insertions and/or have undergone sufficient training for levonorgestrel IUS insertion.
Levosert® IUS contains the same total amount of levonorgestrel with the same release profile as an existing levonorgestrel-containing IUS at a lower unit cost.
It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care. **FTeam**

At this point of the meeting membership reached quorum. The Chairman reviewed the previous positions and the Group ratified the decisions.

6.1. LONG-ACTING REVERSIBLE CONTRACEPTION (CONTINUED)

The Group noted:
- there are no suggested changes to the current formulary choice progestogen-only LARCs, or Cu-IUDs
- another Cu-IUD is available – an intrauterine ball - IUB™ SCu300B MIDI
- the IUB™ SCu300B MIDI:
  - consists of copper beads, with a total exposed copper surface of 300mm², strung on a flexible PET-coated frame
  - is licensed for intrauterine contraception up to 5 years, and costs £38.00 (ex VAT)
- the Faculty of Sexual and Reproductive Healthcare (FSRH) new product review of the IUB™ SCu300B MIDI advises that robust independent studies are lacking (FSRH Clinical Effectiveness Unit, 2019)
- local specialists do not support use of the IUB™ SCu300B MIDI

Taking account of local specialist's recommendations and the FSRH review the Group agreed that the IUB™ SCu300B MIDI should be noted as non-formulary.

Intrauterine ball (IUB™) SCu300B MIDI is not routinely available in NHS Grampian.
Indication under review: intrauterine contraception.
Not routinely available in NHS Grampian. **FTeam**

6.2. ZOVIRAX® (ACICLOVIR) 3% EYE OINTMENT DISCONTINUATION

The Group discussed the SBAR outlining the discontinuation of Zovirax® 3% ophthalmic ointment.

Ms Doney confirmed that:
- the Ophthalmology Service and Pharmacy colleagues in the adult and paediatric services are supportive of options in the Specialist Pharmacy Service (SPS) document "Discontinuation of Zovirax (aciclovir) eye Ointment" (https://www.sps.nhs.uk/articles/shortage-of-aciclovir/)
- the AMT discussed the SPS document and supported the change to ganciclovir 0.15% eye gel as a first-line option and trifluorothymidine eye drops [unlicensed product] as a possible second-line agent
- the Antibiotic Pharmacists confirmed that local empirical guidance (adults) includes only a first-line treatment option and will be updated (promoting ganciclovir to first-line, there are no plans to include a second-line option in the guidance)
- ganciclovir is currently included on the formulary as a second-line option and at points over the last few years it has been used first-line (when supplies of aciclovir 3% eye ointment were limited or exhausted)
- ganciclovir is approximately twice the cost of aciclovir (£19.99/5g vs. £9.34/4.5g, ex VAT)

The Group noted that:
- unlike aciclovir 3% eye ointment, ganciclovir 0.15% eye gel (Virgan®) is not licensed for children and adolescents [because no specific studies have been conducted in this age group]
- the paediatric service uses systemic aciclovir for children, topical aciclovir is seldom

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used
- the Virgan® Summary of Product Characteristics (SmPC) advises that for women of childbearing age, contraceptive measures should be used – but no timeframe specified. Men taking Virgan® are advised to use condoms during treatment and for up to three months after use.
- there is very little information available for trifluorothymidine 1% eye drops (beyond that noted in the SPS document). A Quality Assurance unlicensed medicine risk assessment is not available for the Stockport product.
- the cost of trifluorothymidine 1% eye drops is significantly higher than ganciclovir, and supplies may be subject to additional costs, i.e. delivery charges

The Group discussed:
- the contraceptive precautions noted in the Virgan® SmPC.
- if systemic aciclovir would be an option for adults, rather than an unlicensed topical product

Mr Rore confirmed that the advice [for ganciclovir; Virgan®] is based on animal studies and high doses. This is a cautious line from the company however, it is a valid concern, as there are no data to say otherwise. The UK Teratology Information Service does not have a monograph for ganciclovir. Three months would be considered a sperm cycle and may explain the advice for men.

The Group agreed that the contraceptive precautions noted in the Virgan® SmPC should be highlighted to prescribers and dispensers. Ms Doney will discuss with the AMT and the Ophthalmology Service, with a view to highlighting the advice on the formulary and issuing information to prescribers and Community Pharmacies. **FD**

Mr Rore will check for data regarding penetration of systemic aciclovir into the eye. **CR**

The Group accepted ganciclovir as a first-line treatment option, and as noted in the SPS document, if this is not considered a suitable treatment option, specialists should be consulted on use of the unlicensed product (trifluorothymidine), which is a significantly more costly treatment than ganciclovir. Advice should also be sought from specialists on the management of cases for whom these treatment options are not suitable.

The Group accepted the restricted local need for ganciclovir 0.15% eye gel as a first-line local treatment option for ocular herpes simplex infection.

SBAR - Ganciclovir 0.15% eye gel (Virgan®) is routinely available in line with local guidance.
Indication under review: in line with the local empirical guidance as a first-line treatment option for the treatment of adults with acute herpetic keratitis (dendritic and geographic ulcers).
It was reclassified as 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care. **FTeam**

6.3. DAKLINZA® (DACLATASVIR DIHYDROCHLORIDE)

The Chairman confirmed that daclatasvir, a hepatitis C medicine, has been discontinued in the UK and the formulary entry updated appropriately.

7. OTHER BUSINESS

7.1. EUROPEAN MEDICINES AGENCY (EMA) ADOPTS POSITIVE OPINION FOR MERCK'S KEYTRUDA® (PEMBROLIZUMAB) FOR SIX-WEEK DOSING SCHEDULE ACROSS ALL CURRENT MONOTHERAPY INDICATIONS

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

The Group noted:
- the EMA has recommended the approval of a new extended dosing schedule for pembrolizumab for all approved monotherapy indications in the European Union
- this potential additional licensed regimen will not be assessed by SMC

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- if adopted the less frequent administration schedule will have positive benefits for service delivery and patients receiving pembrolizumab monotherapy
- if the recommendation is accepted the service will move to the extended dosing schedule

The Group agreed that a new 6-week extended dosing schedule for pembrolizumab monotherapy indications would provide significant benefits to patients and the Oncology, Haematology and Aseptic services.

The Group accepted the local need for the pembrolizumab monotherapy 6-week extended dosing schedule without the need for a submission. This position is subject to publication of a final decision by the European Commission/MHRA. **FTeam**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2120 - PERTUZUMAB (HER POSITIVE METASTATIC OR LOCALLY RECURRENT UNRESECTABLE BREAST CANCER)

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

The Group considered the request for pertuzumab in combination with trastuzumab and docetaxel, as a first-line treatment option for adults with HER2-positive metastatic or locally recurrent unresectable breast cancer.

The Group noted:

- this is the third resubmission for pertuzumab for this indication
- pertuzumab [for this indication; used in combination with trastuzumab and docetaxel]:
  - is administered as an 840mg intravenous (IV) infusion over 60 minutes, then 420mg IV infusion over 30 to 60 minutes every three weeks until disease progression or unmanageable toxicity. An observation period of 30 to 60 minutes is recommended after each dose of pertuzumab and before commencement of any trastuzumab or docetaxel infusions. The medicines should be administered sequentially, pertuzumab and trastuzumab may be given in any order, but docetaxel should be administered after these.
  - prolongs progression-free survival and overall survival, and delays the time before the next line of therapy
  - meets SMC orphan-equivalent criteria, and was accepted for use in NHS Scotland following the output from the PACE process and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
- is an extra agent given in combination with a current first-line (doublet) treatment option
- is an additional cost and would have service implications (increased chair time, nursing time and aseptic preparation)
- the high cost of treatment, and that this would represent a new cost to the Health Board
- the SMC advice takes account of the benefits of PASs that improves the cost-effectiveness of pertuzumab and trastuzumab

The Group supported the restricted local need for pertuzumab in combination with trastuzumab and docetaxel, in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

SMC 2120 - Pertuzumab 420mg concentrate for solution for infusion (Perjeta®) is routinely available in line with national guidance (SMC 2120).
Indication under review: in combination with trastuzumab and docetaxel, in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.
Addition of pertuzumab to current first-line treatment, trastuzumab plus docetaxel, significantly increased progression-free and overall survival for women with HER2-positive metastatic or locally recurrent unresectable breast cancer. This advice takes account of the benefit of Patient Access Schemes (PAS) that improves the cost effectiveness of pertuzumab and trastuzumab IV (Herceptin®). This advice is contingent upon the continuing availability of these PAS in NHS Scotland or list prices that are equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.

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It was classified 1b- available for restricted use under specialist supervision and 8a – licensed for hospital use only.
Therapy should only be initiated under the supervision of a physician experienced in the administration of anti-cancer agents. It should be administered by a healthcare professional prepared to manage anaphylaxis and in an environment where full resuscitation service is immediately available.
Patients must have HER2-positive tumour status, defined as a score of 3+ by immunohistochemistry (IHC) and / or a ratio of ≥2.0 by in situ hybridisation (ISH) assessed by a validated test. To ensure accurate and reproducible results, the testing must be performed by a specialised laboratory, which can ensure validation of the testing procedure. **FTeam**

8.2. FG1 416/18 - NALOXONE (NYXOID®) NASAL SPRAY (EMERGENCY TREATMENT FOR OPIOID OVERDOSE)

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

The Group considered the request from the Specialist Pharmacist in Substance Misuse for naloxone nasal spray (Nyxoid®) as emergency therapy for known or suspected opioid overdose.

The Group noted:
- naloxone is an opioid antagonist used as an emergency antidote for overdose caused by opiates/opioids
- currently naloxone as pre-filled syringes for intramuscular administration (Prenoxad®) is supplied to people at risk of opioid overdose, significant others and services in contact with those at risk
- naloxone 1.8mg nasal spray (Nyxoid®):
  - is licensed, for adults and adolescents aged 14 years and older, for the immediate administration as emergency therapy for known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression in both non-medical and healthcare settings
  - is administered at a recommended dose of 1.8mg into one nostril (one nasal spray). In some cases, further doses may be necessary.
  - is considered outwith SMC remit as the product is used for the acute treatment of poisoning
  - provides an additional treatment option, and the needle-free preparation may widen the acceptability/availability of naloxone to people at risk of opioid overdose

The Group accepted the restricted local need for Nyxoid® nasal spray as licensed for emergency therapy for known or suspected opioid overdose. Use would be in line with current processes/governance arrangements and is subject to the Drug Treatment Service providing updated guidance for the supply of naloxone and updated training and advice to people when supplying naloxone. **DTS**

FG1 416/18 - Naloxone (as hydrochloride dihydrate) 1.8mg nasal spray, solution in a single-dose container (Nyxoid®) is routinely available in line with local guidance.
Indication under review: adolescents and adults aged 14 years and over for immediate administration as emergency therapy for known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression in both non-medical and healthcare settings.
It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care. **FTeam**

8.3. SMC 1245/17 - BUPRENORPHINE ORAL LYOPHILISATE (ESPRANOR®) - (SUBSTITUTION TREATMENT FOR OPIOID DRUG DEPENDENCE)

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

The Group considered the request from the Specialist Pharmacist in Substance Misuse for a new oral lyophilisate formulation of buprenorphine (Espranor®), as an alternative option when current formulations are problematic, e.g. prison administration and diversion of

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standard release buprenorphine or in place of standard formulations in Community Pharmacy where dissolution times are excessive

The Group noted:

- Espranor®:
  - is available as 2mg and 8mg oral lyophilisate. It has a lower starting dose and maximum dose [than other buprenorphine products], 2mg and 18mg respectively.
  - has a higher bioavailability than other buprenorphine products, and is not interchangeable with other buprenorphine products
  - should be placed on the tongue not under it. Swallowing should be avoided for 2 minutes and food or liquids must not be consumed for 5 minutes after dissolution.
  - rapidly disperses on the tongue, has a faster dissolution time than other products which may be beneficial in patients who require supervised administration
  - is only appropriate for supervised self-administration, it is not suitable for "take home" dispensing
- Suboxone® is NHS Grampian's current recommended buprenorphine product as it includes the opioid antagonist naloxone in a sublingual (SL) tablet
- generic buprenorphine SL tablets are available at lower cost
- if accepted to formulary, Espranor® would become an additional treatment option and the local guidance updated [Grampian Guidance for the use of buprenorphine and buprenorphine with naloxone for the treatment of opioid dependence]
- Healthcare staff may need to be trained to administer Espranor® correctly particularly where buprenorphine is administered at the same time as other medicines
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of Espranor®

The Group accepted the restricted local need for buprenorphine oral lyophilisate tablets (Espranor®) as an alternative buprenorphine formulation in substitution treatment for opioid drug dependence. Use is subject to the Drug Treatment Service providing updated prescribing guidance and updated training/advice to people when supplying/administering Espranor®. **DTS**

SMC 1245/17 - Buprenorphine 2mg, 8mg oral lyophilisate (Espranor®) is routinely available in line with local guidance.
Indication under review: substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Treatment with buprenorphine oral lyophilisate is intended for use in adults and adolescents aged 15 years or over who have agreed to be treated for addiction.
Restriction: to patients in whom methadone is not suitable.
In patients who require supervised consumption of buprenorphine, the oral lyophilisate formulation has the advantage of a faster dissolution time compared to other available buprenorphine preparations.
Prescribers should be aware that buprenorphine preparations are not interchangeable.
Generic buprenorphine sublingual tablets are available at lower cost.
This advice takes account of the benefit of a Patient Access Scheme (PAS) that improves the cost effectiveness of buprenorphine oral lyophilisate and is contingent upon the continuing availability of the PAS in NHS Scotland or a 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. Treatment should be under the supervision of a clinician experienced in the management of opiate dependence/addiction. **FTeam**

The Group noted the request from the Expert Advisory Group for Medicines in Prisons (EAGfM) asking NHS Board Area Drug and Therapeutic Committees to consider measures to prevent the illicit diversion of buprenorphine within prison settings, assist in health protection and free up clinician time.

Ms Doney will reply to the EAGfM confirming that NHS Grampian supports prescribing Espranor®. **FD**

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8.4. SMC 1320/18 - CIPROFLOXACIN EAR DROPS CETRAXAL® (OTITIS EXTERNA/MEDIA)

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

The Group considered the request for Cetraxal® ear drops.

The Group noted:
- Cetraxal®:
  - is a licensed ciprofloxacin ear drop (0.2%) that will replace the off-label use of ciprofloxacin eye drops 0.3%
  - is licensed for the treatment of acute otitis externa in adults and children > 1 year with an intact tympanic membrane, caused by ciprofloxacin susceptible microorganisms
- off-label use of ciprofloxacin 0.3% eye drops in the ear was previously accepted to formulary as a second-line choice for otitis externa and otitis media
- costs will increase but the increase is not significant

The Group accepted the restricted local need for Cetraxal® ear drops as a replacement for off-label use of ciprofloxacin eye drops 0.3%.

SBAR - Ciprofloxacin 2mg/mL ear drops solution single-dose container (Cetraxal®) is routinely available in line with local guidance.
Indications under review: adults and children older than 1 year with an intact tympanic membrane
1) treatment of acute otitis externa caused by ciprofloxacin susceptible microorganisms (SMC 1320/18).
2) (off-label) treatment of otitis media when gentamicin is contraindicated.
Restriction: when unlicensed ciprofloxacin formulations would otherwise be used.
It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.
Consideration should be given to official guidance on the appropriate use of antibacterial agents. **FTeam**

8.5. FG1 407/17 - APREPITANT AND FG1 411/18 NETUPITANT/PALONOSETRON (PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH AC REGIMENS, BREAST CANCER PATIENTS)

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

The Group discussed the proposed use of aprepitant and Akynzeo® as possible first-line antiemetic treatment options for a group of breast cancer patients receiving highly emetogenic anthracycline plus cyclophosphamide (AC) combination chemotherapy.

Ms Galvin confirmed that:
- aprepitant and Akynzeo® are requested as first-line options for this highly emetogenic AC combination chemotherapy regimen
- in breast cancer patients there is a high antiemetic failure rate with this particular AC combination chemotherapy regimen
- if available first-line, rather than for failure, this would reduce the amount of post treatment steroids patients would receive
- the service would like the option to use either agent and is promoting screening patients to identify patients at a high risk of emesis
- Akynzeo® is a one-off dose and convenient for patients and the service, aprepitant is a 3-day regimen

The Group noted:
- that the particular AC chemotherapy regimen used is highly emetogenic
- aprepitant is licensed for the requested indication, however use of Akynzeo® would be off-label
- availability of effective first-line antiemetic options would provide a significant benefit for patients
- aprepitant is due to come off patent later this year, and antiemetic choices would be reviewed if generic options become available

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Aprepitant 80mg, 125mg hard capsules (EMEND®) is routinely available in line with regional guidance.
Indication under review: for the prevention of acute and delayed nausea and vomiting associated with anthracycline plus cyclophosphamide combination regimens used in breast cancer patients, in line with regional guidance.
It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. **FTeam**

Akynzeo® 300mg/0.5mg hard capsules (netupitant/palonosetron)▼ is routinely available in line with regional guidance.
Indication under review: (off-label use) for the prevention of acute and delayed nausea and vomiting associated with anthracycline plus cyclophosphamide combination regimens used in breast cancer patients, in line with regional guidance.
It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. **FTeam**

8.6. FG1 418/19 - STRONTIUM RANELATE ARISTO® (SEVERE OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN)

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

The Group considered the request to include strontium ranelate 2g granules on the formulary for post-menopausal women with severe osteoporosis.

The Group noted:
- strontium ranelate 2g granules:
  - was previously available as the brand Protelos®▼ and the request for formulary inclusion is in line with the previous formulary positioning of Protelos®▼
  - is licensed for post-menopausal women and men at a high risk osteoporosis, but the request for formulary inclusion is only for post-menopausal women
  - is included in the current SIGN guidance for osteoporosis
  - as Aristo®, is more than twice the previous cost of Protelos®▼
- patient numbers will be small (e.g. marked fracture risk and other agents contraindicated), and recommendations for treatment will only come from the specialist service/physicians experienced in the treatment of osteoporosis
- the specialist service will advise on the side-effect profile and risk/benefit of use, give patients the alert card, and arrange for patient follow-up and monitoring

The Group accepted the restricted local need for strontium ranelate Aristo®▼ 2g granules as a possible last line therapy for postmenopausal women with severe osteoporosis.

FG1 418/19 - Strontium ranelate Aristo®▼ 2g granules for oral suspension is routinely available in line with local guidance.
Indication under review: for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture, for whom treatment with other medicinal products approved for the treatment of osteoporosis is not possible due to, for example, contraindications or intolerance.
In postmenopausal women, strontium ranelate reduces the risk of vertebral and hip fractures. The decision to prescribe strontium ranelate should be based on an assessment of the individual patient's overall risks. 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. Treatment should only be initiated by a physician with experience in the treatment of osteoporosis. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED MARCH 2019

The Group noted the SMC provisional advice issued March 2019.

The Group agreed that the abbreviated SMC advice documents do not require full submissions and summaries will be provided for consideration at the April meeting. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED MARCH 2019

The Group noted the SMC advice published March 2019.

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Following publication of negative SMC recommendation for tisagenlecleucel (Kymriah®) ▼ SMC 2141, this medicine will not be included on the Grampian Joint Formulary for the indication in question.

Following publication of non-submission statements, for rituximab (MabThera®) SMC 2165 and epoetin alfa (Eprex®) SMC 2164, 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 60-day timescale:
- SMC 1338/18 letermovir (Prevymis®) ▼
- SMC 2130 liposomal formulation of daunorubicin/cytarabine (Vyxeos®)

Local advice for these medicines and indications will be included in the March 2019 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTeam**

11. GENERAL INFORMATION FROM SMC MARCH 2019

In February 2019, the marketing authorisation for a formulary medicine Trimbow® (beclometasone dipropionate/formoterol fumarate dihydrate/glycopyrronium) was extended to include use in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist. This change will not be assessed by SMC and the current restriction for SMC advice 1274/17 is still valid.

It was confirmed use locally is in line with the Respiratory Managed Clinical Network (MCN) guidance. The Formulary Team will liaise with the Respiratory MCN to confirm of this licence extension is relevant locally. **FTeam**

12. DOCUMENTS FOR INFORMATION

Items 12.1 (MHRA Drug Safety Update February 2019), 12.2 (Medicine Guidelines and Policies Group - minute December 2018) and 12.3 (Area Drug and Therapeutics Committee Collaborative - newsletter Feb 2019) were noted.

13. AOCB

CONTINGENT/PROVISIONAL FORMULARY ACCEPTANCE

Ms Davie asked if there was a list of medicines and a process to track medicines that have a 'conditional acceptance' to formulary, for example Sayana® Press. Ms Doney confirmed the 'subject to protocol' classification is no longer available and that medicines noted with this classification are known and tracked. However, unlike other medicines Sayana® Press was not subject to provision of a guideline but required a process for waste disposal to be developed. The process was developed and information issued by the Principal Pharmacist, Pharmaceutical Services.

Queries regarding Sayana® Press happen infrequently but regularly, generally following Sexual Health Service training events.

MEXILETINE

Mexiletine is not included on the formulary but there are a small number of patients receiving unlicensed mexiletine as an antiarrhythmic agent.
A new mexiletine preparation, Namuscla® (mexiletine hydrochloride 167mg hard capsules) is now available. Namuscla® is licensed for the symptomatic treatment of myotonia in adult patients with non-dystrophic myotonic disorders, and was designated an orphan medicine by the European Medicines Agency (EMA). It is contraindicated in ventricular or atrial tachyarrhythmia. 100 capsules cost £5,000.

DATE OF NEXT MEETING

Tuesday 16 April 2019 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE _____ **DATE 16 April 2019**