NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 21 May 2019 at 14:30 in the Seminar Room, David Anderson Building

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

ITEM	SUBJECT	ACTION

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

1. APOLOGIES

Apologies for absence were requested and noted.

2. DRAFT MINUTE OF THE MEETING HELD 16 APRIL 2019

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

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

3. PRESENTATION – NONE

Ms Doney reported that a presentation on homecare arrangements is scheduled for the July meeting.

4. MATTERS ARISING

4.1. ACTION LOG

The Chairman reviewed the meeting Action log with the Group to clarify the status of items that were not included on the agenda.

4.2. LIPID-LOWERING GUIDANCE AND CO-ENZYME Q10/VITAMIN D

Ms Doney confirmed that the Group's concerns regarding including mention of vitamin D and co-enzyme Q10 in the local lipid guidance [that this could be misconstrued as tacit agreement to prescribe] have been raised with the author and the Grampian Guidance Intranet team. A response is awaited.

Additionally, the Specialist Pharmacy Service (SPS) recently published an updated Medicines Q&A that evaluates the available evidence on the use of co-enzyme Q10 supplementation to reduce the risk of statin-induced myopathy.
The Q&A document was linked to the statin section of the formulary, and will be emailed to members after the meeting. **FD**

4.3. ILOPROST 100MICROGRAMS/ML – (LICENSED PRODUCT NOW AVAILABLE)

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

The Group discussed the availability of a licensed iloprost concentrate for solution for infusion.

Ms Doney reported that the relevant service areas have confirmed that iloprost infusion is used locally for all of the licensed indications.

The Formulary Group accepted the restricted local need for a licensed iloprost infusion preparation, without the need for a full submission.

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	SBAR - Iloprost 100micrograms/mL concentrate for solution for infusion is routinely available in line with local guidance. **Indications under review: in adults for the treatment of:** • **severe chronic ischaemia of lower limbs in patients at risk of amputation, in whom surgical revascularisation or angioplasty has failed or is not indicated, following an interdisciplinary meeting of physicians, surgeons and radiologists** • **severe Raynaud's phenomena in patients with progressive trophic disorders** **It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only.** **Iloprost 100micrograms/mL concentrate for solution for infusion is NOT ready to use and requires dilution before administration.** **Iloprost 100micrograms/mL concentrate for solution for infusion should be administered under strict monitoring in a hospital or outpatient clinic setting with adequate facilities.**	**FTeam**

4.4. TOFACITINIB HOMECARE ARRANGEMENT FOR PSORIATIC ARTHRITIS AND ULCERATIVE COLITIS

Ms Doney confirmed that the homecare arrangement is dispense and delivery only.

4.5. Bevacizumab for wet AMD

The Group noted the Royal College of Ophthalmologists position, and the information provided regarding the High Court decision, regarding the use of bevacizumab in the treatment of wet AMD.

There are discussions ongoing regarding the use of bevacizumab (Avastin®) in the treatment of wet age-related macular degeneration (wet AMD), and the actions will be taken forward by the Grampian Medicines Management Group (GMMG).

4.6. Single National Formulary

The Single National Formulary (SNF) team confirmed that:
- in September 2018 responsibility for the SNF, within the Scottish Government, transferred to the Medicines Policy Team
- work to date has seen the development of an initial version of a new national formulary web platform. Work will continue to provide a complete content platform ready to receive formulary recommendations.
- a timeline for SNF development activities in 2019-20 will be shared with all stakeholders once confirmed

4.7. North of Scotland Cancer Network (now known as North Cancer Alliance)

The Regional Lead Pharmacist for the North Cancer Alliance (NCA) confirmed that regional review of SMC advice for cancer medicines will be a future development for the NCA, and that the Formulary Group is required to continue to review SMC accepted cancer medicines.

5. FORMULARY GROUP DECISIONS APRIL 2019 - PUBLISHED 30/04/2019

5.1. FORMULARY GROUP DECISIONS APRIL 2019

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

6. NETFORMULARY/FORMULARY REVIEW

6.1. SMC 1273/17 - OLARATUMAB FOR SOFT TISSUE SARCOMA

The Group noted that the European Medicines Agency (EMA) has recommended that the marketing authorisation of olaratumab be revoked.

This position was reached following assessment of the full data from the ANNOUNCE study. The EMA concluded that olaratumab with doxorubicin does not prolong the lives of patients with soft tissue cancer more than doxorubicin alone. The European Commission will issue a final legally binding decision.

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The service stopped using olaratumab following release of the trial data, and the drug was removed from the chemotherapy electronic prescribing system.

The Group supported recording olaratumab as non-formulary pending official withdrawal. **FTeam**

6.2. TRASTUZUMAB IV BIOSIMILAR – HERZUMA®

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

The Group noted that:
- trastuzumab, as the intravenous (IV) formulation (150mg powder for concentrate for solution for infusion), is available as biosimilar products and the reference product (Herceptin®)
- trastuzumab, as a subcutaneous injection (S/C), is only available as the brand Herceptin® (600mg solution for injection) manufactured by Roche
- trastuzumab emtansine (Kadcyla®) is a combined trastuzumab and chemotherapy treatment, that is manufactured by Roche
- there is a national framework for trastuzumab IV, and as NHS Grampian uses vials and compounded trastuzumab the preferred product is Herzuma® manufactured by Napp
- trastuzumab in a S/C formulation is not available as biosimilar products, and the choice remains Herceptin® S/C
- there is a risk of medication errors with trastuzumab (as the reference or biosimilar products) and trastuzumab emtansine, but the current risk materials for Kadcyla® do not include biosimilar medicines

Ms Galvin reported that to reduce the risk of confusion between the different products, the proposal is to only stock one brand of trastuzumab IV. The planned introduction of Herzuma® will start towards the end of May, and there are service implications with the use of the IV preparation. The electronic records will specify the brand name and formulation to try to minimise the risk of confusion.

The local position with regard to biosimilar medicines is that - As the efficacy and safety of biosimilar medicines is established through the medicines' regulatory processes, biosimilar medicines should be available for prescribing within NHS Grampian without the need for individual formulary submissions if the original reference product is already on formulary. This position is subject to compliance with the relevant monitoring and governance requirements of a biosimilar medicines prescribing framework.

Ms Doney reported that the EMA, MHRA and Roche have been contacted regarding update of the current Kadcyla® risk materials to include mention of biosimilar products. 14/05/2019 the EMA noted the concerns and confirmed that the risk management plan and Summary of Product Characteristics (SmPC) for Kadcyla® are currently under review.

The Group accepted the restricted local need for Herzuma®, as the preferred biosimilar of IV trastuzumab 150mg, without the need for a full submission. Herzuma® is accepted as a treatment option within treatment pathways for appropriate patients as identified by treating clinicians and subject to compliance with a biosimilar medicines prescribing framework.

Herzuma® ▼ 150mg powder for concentrate for solution for infusion (trastuzumab) is routinely available in line with national guidance (previous SMC/HIS advice for intravenous trastuzumab).
Indications under review:

1) Breast cancer
For the treatment of adult patients with HER2 positive metastatic breast cancer (MBC) and early breast cancer (EBC) in a range of settings (excluding its use in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive MBC, not previously treated with trastuzumab).
Trastuzumab should only be used in patients with metastatic or early breast cancer whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay.

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2) Metastatic gastric cancer (MCG)
In combination with capecitabine or 5-fluorouracil and cisplatin for the treatment of adult patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease.
Restriction: for use in patients whose tumours have HER2 overexpression defined by immunohistochemistry (IHC) 3+ ("HER2 high expresser").
Herzuma® should only be used in patients with MGC whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory SISH or FISH result, or by an IHC 3+ result, as determined by an accurate and validated assay. Accurate and validated assay methods should be used.

It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. Herzuma® 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 Herzuma® 150mg (trastuzumab IV) and not Kadcyla® (trastuzumab emtansine) or Herceptin® 600mg subcutaneous injection (trastuzumab S/C). **FTeam**

Biological medicines, including biosimilar medicines, should be prescribed by both generic and brand name and the trade name and batch number should be recorded on the patient's prescription, case record or other appropriate clinical system.

6.3. OFATUMUMAB FOR CHRONIC LYMPHOCYTIC LEUKAEMIA

The Group noted that last year Novartis withdrew ofatumumab, for chronic lymphocytic leukaemia (CLL), from markets outside the United States due to low numbers of patients using the treatment. Compassionate use programmes were set up so that patients could continue treatment, and development for other indications is continuing.

The service is aware of the withdrawal and the formulary entry will be recorded as non-formulary. As compassionate use programmes may be available, the Specialist Pharmacy Service (SPS) information will be linked to the formulary entry.

Ofatumumab is now withdrawn from use in the European Union.
Indications:
- Previously untreated chronic lymphocytic leukaemia (CLL): in combination with chlorambucil or bendamustine for the treatment of adult patients with CLL who have not received prior therapy and who are not eligible for fludarabine-based therapy.
- Relapsed CLL: in combination with fludarabine and cyclophosphamide for the treatment of adult patients with relapsed CLL.
- Refractory CLL: for the treatment of CLL in adult patients who are refractory to fludarabine and alemtuzumab.
In view of the withdrawal, ofatumumab has been removed from the Grampian Joint Formulary. **FTeam**

6.4. CONTRACEPTION (UPDATE RE LEVOSERT® AND FSRH GUIDANCE)

Ms Doney confirmed that there is now a confidential Primary Care discount available for any prescriptions issued for Levosert® (52mg levonorgestrel intrauterine device). Ms Doney will highlight the availability of a confidential discount price to the Primary Care Prescribing Group. **FD**

The Faculty of Sexual and Reproductive Healthcare (FSRH) has updated its guidance for progestogen-only pills. The guidance will be reviewed and information will only come back to Group if formulary implications are identified.

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7. OTHER BUSINESS

7.1. CLINICAL MANAGEMENT OF BREAST CANCER IN NHS TAYSIDE

The Group noted the content of the Healthcare Improvement Scotland (HIS) inspection and clinical risk assessment reports.

The Chairman stated that, when appropriate, and where a NCA clinical management guideline is not available, the Formulary Group would review requests for the use of cancer medicines/treatment regimens within NHS Grampian.

7.2. VALPROATE MEDICINES AND SERIOUS HARMS IN PREGNANCY

The Group noted the availability of an updated annual risk acknowledgement form and guidance from professional bodies to support compliance with the valproate pregnancy prevention programme.

Ms Doney confirmed that the specialist services are aware of the updated information.

7.3. FORMULARY APPLICATION FORMS (FG1SMC, FG1 AND FGA)

Ms Doney reported that the current formulary application forms were reviewed, with a view to harmonising the forms. Only minor changes were made.

7.4. UPDATE TO SCOTTISH PALLIATIVE CARE GUIDELINES MARCH 2019

The Group noted the selective update to the Scottish Palliative Care Guidelines. The update includes one new guideline on the management of end stage liver disease; a refresh of guidance on the use of the CME T34 Syringe Pumps and a number of new medicine information sheets.

The Specialist Palliative Care Pharmacist confirmed there are no real implications from the guidelines update, the 'local' anticipatory prescribing guidance is already compliant, and the new medicine information sheets are useful.

The formulary will be updated in line with recommendations of the Specialist Palliative Care Pharmacist. **FTeam**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2104 - ANAKINRA (STILL'S DISEASE, INCLUDING SJIA)

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

The Group considered the request for anakinra for infants, children and adolescents for the treatment of Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA).

It was confirmed that anakinra is licensed for use in adults, adolescents, children and infants from 8 months of age. However, the adult service has not provided information regarding use in adult-onset Still's disease so the submission only relates to use in paediatric patients.

The Group noted:

- anakinra:
  - is an interleukin-1 inhibitor
  - is not included on the formulary for any other indication
  - provides a licensed treatment option for Still's disease and meets SMC orphan equivalent criteria for this indication
  - [for this indication] can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying anti-rheumatic drugs (DMARDs)
  - is given as a daily subcutaneous injection and this may limit acceptability to patients. The most frequently reported adverse reaction is injection site reactions.
  - may be of particular value in patients who are acutely unwell and in macrophage activation syndrome (MAS)

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- licensing is based on small patient numbers, and the licensed indication is broader than the evidence in the ANAJIS study. The study did not include patients aged between eight months up to two years, and excluded patients treated with DMARDs.
- that the one month double blind treatment phase of the ANAJIS study was too short to evaluate the medium- and long-term impact of anakinra on sJIA
- there are no head-to-head data against biologic comparators, e.g. tocilizumab
- use will be in line with national guidance from the Scottish Paediatric and Adolescent Rheumatology Network (SPARN)
- patient numbers are expected to be low
- there is not a pharmaceutical company sponsored homecare agreement, if homecare is required it would have to be accessed through the national framework and would incur additional costs

The Group accepted the restricted local need for anakinra within the paediatric service for the treatment of Still's disease (including sJIA) in infants, children and adolescents from 8 months to < 18 years of age.

SMC 2104 - Anakinra 100mg/0.67mL (150mg/mL) solution for injection in pre-filled syringe (Kineret®) is routinely available in line with national guidance (SMC 2104). Indication under review: in adolescents, children and infants aged eight months to < 18 years of age with a body weight of 10kg or above for the treatment of Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. Anakinra can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying anti-rheumatic drugs (DMARDs). 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 specialist physicians experienced in the diagnosis and treatment of Still's disease. **FTeam**

8.2. FG1SMC 1338/18 - LETERMOVIR (CMV PROPHYLAXIS AFTER ALLOGENIC HSCT)

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

The Group considered the request for letermovir for the prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients of an allogeneic haematopoietic stem cell transplant (HSCT).

The Group noted:

- letermovir:
  - is the first in a new class of antivirals that inhibit the CMV DNA terminase complex. The recommended dose is 480mg daily, should be started after HSCT (may be started on the day of transplant and no later than 28 days post-transplant) and should continue through the first 100 days post HSCT.
  - is the first medicine licensed for the prophylaxis of CMV reactivation and disease in adult CMV-seropositive recipients of HSCT
  - [for this indication] has an orphan medication designation from the European Medicines Agency (EMA), meets SMC ultra-orphan equivalent criteria, and was accepted for use in NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers
  - is not licensed for any other indications or for use in solid organ transplantation
  - reduces the risk of CMV reactivation [if given through the first 100 days post HSCT transplant]
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of letermovir
- the safety and efficacy of use for more than 100 days has not been studied in clinical trials. Prolonged prophylaxis beyond 100 days post-transplant may be of benefit in some patients at high risk for late CMV reactivation, but use is currently unlicensed.
- the reactivation rate of CMV in allograph is very high and there are currently no licensed, or other effective therapies, for the prevention of reactivation of CMV post-transplant. High dose aciclovir [off-label] is used but has a high failure rate.

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- all allogeneic transplants are carried out in Glasgow, and prophylaxis with letermovir will be initiated and supplied by the transplant centre
- when patients return from Glasgow (~ 5-6 weeks post-transplant) care is shared with the local centre. A local process will be needed to supply letermovir if patients are unable to return to Glasgow for repeat supplies.
- treatment will only be supplied from hospital, it is not appropriate for prescribing in Primary Care and a ScriptSwitch message should be deployed for this medicine **AD/FD**

The Group accepted the restricted local need for letermovir for the prophylaxis of CMV reactivation and disease in adult CMV-seropositive recipients of an allogeneic HSCT.

SMC 1338/18 - Letermovir 240mg film-coated tablets (Prevymis®) ▼ is routinely available in line with national guidance (SMC 1338/18).
Indication under review: for prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic haematopoietic stem cell transplant (HSCT).
Letermovir, compared with placebo, reduced the incidence of CMV reactivation and disease in CMV-seropositive adults undergoing allogeneic HSCT.
This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of letermovir and is contingent upon the continuing availability of the PAS in NHS Scotland or a 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. Consideration should be given to official guidance on the appropriate use of antiviral agents. Treatment should be initiated by a physician experienced in the management of patients who have had an allogeneic haematopoietic stem cell transplant. **FTeam**

Ms Davie raised a query regarding the use of valganciclovir for kidney transplant patients - clarity about the group of patients that are eligible for treatment and the length of treatment. The specific queries will be investigated and information brought to the next meeting. **AD/FD**

8.3. FG1SMC 2130 - LIPOSOMAL DAUNORUBICIN/CYTARABINE (NEWLY DIAGNOSED THERAPY-RELATED T-AML OR AML WITH MYELODYSPLASIA-RELATED CHANGES)

Dr Culligan declared a person specific interest in relation to this medicine and took no part in the discussion or decision-making. However, at the invitation of the Chairman, Dr Culligan provided members with some background regarding the treatment of acute myeloid leukaemia and the use of Vyxeos®.

The Group considered the request for Vyxeos® for the treatment of adults with newly diagnosed, therapy-related acute myeloid leukaemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

The Group noted:
- Vyxeos®:
  - is a liposomal formulation of a fixed combination of daunorubicin and cytarabine. The 1:5 molar ratio has been shown to maximise synergistic anti-tumour effects in AML.
  - is given as induction (and consolidation) and provides better overall survival
  - has been designated an orphan medicine by the EMA for the treatment of AML, and meets SMC end of life and ultra-orphan criteria
  - leads to prolonged cytopenias, but is quite well tolerated and does not appear to cause as much tissue damage (mucositis)
  - was accepted for use in NHS Scotland after application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
- the service has experience of use of this medicine, as individual treatment requests (licensed indication) and within AML clinical trials (use outside the licence)
- treatment should be continued as long as the patient continues to benefit or until disease progression up to maximum of two induction courses
- the poor prognosis of secondary AML

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- the age range in the trial was 60-75 years, but treatment would not be limited by chronological age
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of Vyxeos®
- patient numbers are expected to be low

The Group accepted the restricted local need for Vyxeos® for the treatment of adults with newly diagnosed, t-AML or AML-MRC, as outlined in SMC 2130.

SMC 2130 - Liposomal formulation of daunorubicin/cytarabine 44mg/100mg powder for concentrate for solution for infusion (Vyxeos®) is routinely available in line with national guidance (SMC 2130).
Indication under review: for the treatment of adults with newly diagnosed, therapy-related acute myeloid leukaemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of liposomal daunorubicin/cytarabine 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 8b – recommended for hospital use only. Treatment should be initiated and monitored under the supervision of a physician experienced in the use of chemotherapeutic medicinal products.
Vyxeos® (liposomal daunorubicin/cytarabine) has a different posology than daunorubicin injection and cytarabine injection and it must not be interchanged with other daunorubicin and/or cytarabine containing products. **FTeam**

8.4. FG1SMC 1240/17 - NIVOLUMAB (CHL AFTER ASCT)

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

The Group considered the request for nivolumab monotherapy for adults with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin.

The Group noted:
- nivolumab:
  - is already included in the formulary for other indications, and would be the second checkpoint inhibitor available for the treatment of cHL
  - [for this indication] is given as monotherapy, as an infusion every two weeks, and there is no maximum duration of treatment
  - [for this indication] meets SMC ultra-orphan and end of life criteria, and was accepted for use in NHS Scotland following the output from the PACE process and application of the appropriate SMC modifiers
  - will be used infrequently and patient numbers will be very low
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of nivolumab
- pembrolizumab is also available for cHL (with a two-year stopping rule), however the licensed indications for the two checkpoint inhibitors are marginally different, and the service would not sequence the two medicines

The Group accepted the restricted local need for nivolumab monotherapy for the treatment of relapsed or refractory cHL in line with SMC 1240/17.

SMC 1240/17 - Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) ▼ is routinely available in line with national guidance (SMC 1240/17).
Indication under review: as monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin.
In an open-label, single-arm study, a clinically meaningful objective response rate was achieved in patients with relapsed or refractory cHL treated with nivolumab.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that

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improves the cost effectiveness of nivolumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment must be initiated and supervised by physicians experienced in the treatment of cancer. **FTeam**

8.5. FG1 415/18 - TOLVAPTAN (HYPONATRAEMIA SECONDARY TO THE SIADH)

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

The Group considered the request from Endocrinology for the use of tolvaptan, as the brand Samsca®, for the treatment of hyponatraemia secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH).

The Group noted that:

- tolvaptan:
  - is a selective vasopressin V2-receptor antagonist that is available as the brands Samsca® and Jinarc®
  - as Jinarc®, is included on the formulary for restricted use for autosomal dominant polycystic kidney disease in adults with chronic kidney disease stage 1 to 3 at initiation of treatment with evidence of rapidly progressing disease in line with SMC 1114/15 (SMC advice subject to PACE process)
  - as Samsca®, is licensed for the treatment of adults with hyponatraemia secondary to SIADH at a dose of 15mg to 60mg orally once a day. Samsca® is not accepted for use within NHS Scotland due to the absence of a submission from marketing authorisation holder (SMC 605/10).
  - as Samsca®, is currently recorded as non-formulary with a warning message regarding the risk of confusion with Jinarc®
- the potential for significant adverse effects, and that an over-rapid increase in serum sodium can cause serious neurological events
- licensing is based on two trials that included very small numbers of patients with a diagnosis of SIADH and a short treatment period (30 days)
- the length of treatment/maximum length of treatment is not specified, there is minimal research to support long-term use, and in 2013 the U.S. Food & Drug Administration (FDA) limited the duration of Samsca® treatment to 30 days
- hyponatraemia secondary to SIADH is commonly seen in lung cancer, pneumonia
- it is likely that treatment would be required urgently and that patients would be quite unwell, but there are processes to access medicines that are not included on the formulary

It was reported that:

- the submission suggested that treatment would be initiated following advice from endocrinology or oncology. However, oncology would seek advice from endocrinology.
- previously there were supply issues with demeclocycline

The Group required clarification of a few points before making a final decision and requested that Dr Abraham attend a meeting to discuss the submission. **FTeam**

Points for clarification:

- when would the use of Samsca® be considered in relation to the use of demeclocycline?
- is there a treatment protocol available? Not only when Samsca® would be considered and which patients it would be considered for, but which clinicians could recommend treatment. [The Group felt that it would be useful to have a treatment protocol that specified the lines of responsibility; the clinical characteristics that would make patients eligible for treatment; clinical criteria for starting/stopping; duration of treatment (is there a maximum length of treatment?)]
- who is responsible for prescribing, dispensing and monitoring, and in what circumstances would it be appropriate to transfer treatment to Primary Care?

The submission and review will be sent to the Renal and Respiratory physicians for comment. **FTeam**

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8.6. FGASMC 2152 - TESTOSTERONE GEL

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

The Group considered the summary of the currently available topical testosterone replacement products.

The Group noted:
- Testavan®:
  - is a topical testosterone gel, one gram contains 20mg of testosterone. The recommended dose is 23mg testosterone (one pump) applied once a day, with a maximum dose of 69mg testosterone (three pumps) per day.
  - [unlike other topical preparations] is applied using the applicator cap (reducing the risk of potential secondary transfer of testosterone)
- that none of the products are licensed for loss of libido only
- the cost of Testavan® is on a par with, or less than, other topical preparations
- the Endocrinology service is supportive of inclusion on the formulary

Ms Doney reported that following transfer of Marketing Authorisation Holder (MAH) Testim® gel will be marketed in the UK again, however the cost of Testim® is unknown.

The Group accepted the restricted local need for Testavan® testosterone transdermal gel as an additional topical testosterone replacement therapy for adult male hypogonadism, without the need for a full submission.

SMC 2152 - Testosterone 20mg/g transdermal gel (Testavan®) is routinely available in line with national guidance (SMC 2152).
Indication under review: testosterone replacement therapy for adult male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests.
Restriction: patients requiring a transdermal delivery system.
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 MAY 2019

The Group noted the SMC provisional advice issued May 2019.

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

FINGOLIMOD PAEDIATRIC EXTENSION

The Group requested that a summary is provided for review at a future meeting (full submission not required). **FD**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED MAY 2019

The Group noted the SMC advice published May 2019.

Following publication of the not recommended advice, for Xonvea® SMC 2140, and the non-submission statements, for chenodeoxycholic acid SMC 2190, daratumumab SMC 2191, dasatinib SMC 2192 and rituximab SMC 2193, 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 2135 and SMC 2179 abemaciclib (Verzenios®)▼
- SMC 2137 cariprazine (Reagila®)▼
- SMC 2159 latanoprost plus timolol (Fixapost® Preservative Free Eye Drops)
- SMC 2144 pembrolizumab (Keytruda®)▼

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

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11. GENERAL INFORMATION FROM SMC MAY 2019 - NONE

12. DOCUMENTS FOR INFORMATION

Items 12.1 (MHRA Drug Safety Update April 2019), 12.2 (MEDwatch (May 2019)), 12.3 News from SMC (flash report March 2019), 12.4 (Antimicrobial Management Team Meeting minute February 2019) and 12.5 (Grampian Medicines Management Group minute January 2019) were noted.

13. AOCB

HYDROCHLOROTHIAZIDE RISK OF NON-MELANOMA SKIN CANCER (DRUG SAFETY UPDATE)

Ms Doney reported that last month the hydrochlorothiazide information was issued to the Health and Social Care Partnership (HSCP) Lead Pharmacists, however following feedback from a Practice Pharmacist the table of products has been updated.

The initial table of hydrochlorothiazide-containing products was based on 2018 PRISMs data. However, the data filter did not find any hydrochlorothiazide-containing products that have a British Approved Name. The updated table now includes all preparations currently available in UK (based on Martindale info, last updated Feb 2019).
Rechecking the 2018 data, the main product missed was co-amilozide, with some prescribing of co-zidacapt.

The Group accepted the updated information for issue to the HSCP Lead Pharmacists. **FD**

DATE OF NEXT MEETING

Tuesday 18 June 2019 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE _____ **DATE 18 June 2019**