NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 16 April 2019 at 14:30 in the Seminar Room, David Anderson Building

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Ms M Galvin	
Ms F Doney	Dr A MacDonald	
Dr L Elliot	Mr C Rore	
Dr J Fitton (from item 4.1)	Mr R Sivewright	
Mrs L Harper	Dr A Sun	
Professor J McLay (Chairman)		
Mrs L Montgomery		
Dr W Moore (from item 4.1)		
Mr M Paterson		

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

The Chairman confirmed that the meeting would go ahead, 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 MARCH 2019

Members accepted the draft note of the meeting subject to correction of the entry for item 9 [removal of reference to SMC not recommended advice and non-submission statements].

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

ITEMS NOT ON THE AGENDA

LIPID-LOWERING GUIDANCE
It was confirmed that the lipid-lowering guidance is available on the intranet, and the availability of the guidance was highlighted in a recent Grampian Guidance Newsletter.

There was concern raised that the guidance mentions that some people take over-the-counter vitamin D and/or co-enzyme Q10 at the same time as statins to reduce side-effects. The validity of this statement was questioned. Ms Doney had already requested that Medicines Information research the evidence for this.

The Chairman requested that this statement is removed from the guidance. **FD**

At this point of the meeting membership reached quorum. The Chairman went over the positions reached earlier, and the Group ratified the previous decisions.

4.1. ACTION LOG (CONTINUED)

PEMBROLIZUMAB MONOTHERAPY 6-WEEK DOSING REGIMEN
Ms Doney reported that the European Commission supported the pembrolizumab 6-week dosing regimen and the Summary of Product Characteristics (SmPC) updated early April.

The Oncology, Haematology and Aseptic services are aware of the regimen change. The consultants are supportive of the extended dosing schedule, however discussions are ongoing regarding the need for a mid-cycle review for some patient groups.

Item closed. **FD**

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4.2. HYDROCHLOROTHIAZIDE (DRUG SAFETY UPDATE)

Members reviewed and accepted the minor amendment to the information (noting chlortalidone as non-formulary).
The information will be sent for inclusion in IMPACT, and the prescribing data highlighted with the Health and Social Care Partnership (HSCP) Lead Pharmacists. **FD**

Ms Doney confirmed that, earlier this month, a list of hydrochlorothiazide-containing preparations was sent for consideration of linking to a ScriptSwitch message.

Item closed. **FD**

4.3. NETFORMULARY SUMMARY OF RECENT FG DECISIONS

This item was discussed with item 6.1.

4.4. GANCICLOVIR 0.15% - HIGHLIGHT CONTRACEPTIVE PRECAUTIONS TO PRESCRIBERS AND DISPENSERS

Ms Doney confirmed that the formulary entry for ganciclovir eye drops is published and includes the contraceptive precautions noted in the Virgan® SmPC.

The Group agreed that the contraceptive precautions noted in the SmPC should be highlighted to:

- prescribers and dispensers by utilising prescribing bulletins, e.g. IMPACT and Community Pharmacy Update
- the Antimicrobial Management Team (AMT) for inclusion in the empirical guidance update
- the Ophthalmology department/Eye Health network **FTeam**

Ms Doney will liaise with the IT Facilitators to escalate an enquiry to the Primary Care prescribing system manufacturers requesting that the Virgan® SmPC contraception warnings are highlighted on General Practice prescribing systems. **FD**

4.5. PENETRATION OF SYSTEMIC ACICLOVIR IN THE EYE

At the March meeting, the Group queried if systemic aciclovir would be another treatment option for adults with ocular herpes simplex infection.

The Group noted the evidence summary provided by Mr Rore regarding the penetration of systemic aciclovir in the eye. The information does not affect the current formulary choices but will be shared with the Antimicrobial Management Team (AMT) and Ophthalmology departments for consideration. **FD**

Item closed. **FD**

5. FORMULARY GROUP DECISIONS MARCH 2019 - PUBLISHED 03/04/2019

5.1. FORMULARY GROUP DECISIONS MARCH 2019

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

5.2. DRAFT NETFORMULARY UPDATE FOR MARCH 2019 FORMULARY GROUP

Ms Doney confirmed that the majority of the March decisions are published and any remaining decisions will be incorporate within the next 2-3 weeks. **FTeam**

Any unpublished decisions from the last financial year will also be included within the next 2-3 weeks. **FTeam**

6. NETFORMULARY/FORMULARY REVIEW

6.1. PROPOSAL FOR PUBLICATION OF DECISIONS IN NETFORMULARY

Ms Doney tabled the draft proposal for publication of Formulary Group decisions. She confirmed that currently safety warnings are included on the website without authorisation

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from the Group.

The Group agreed that the Formulary Team has delegated authority to publish decisions/advice. If an executive decision is required the Chair, Vice-chair and Ms Doney (or a member of the Formulary Team) will agree a course of action and, to ensure transparency of decision-making, any changes actioned will be brought to the next Formulary Group meeting.

Delegated authority to publish decisions is subject to compliance with basic principles:
- the use of standard processes
- safety warnings from the Medicines and Healthcare products Regulatory Agency (MHRA) and European Medicines Agency (EMA) would be included on the website without delay
- transparency of decision-making – assurance provided by regular reporting, including exception reporting if publication timescales are not met

The process and reporting will be reviewed in 3 to 6 months. **FD**

ALEMTUZUMAB
Ms Doney reported that the EMA has started a review of alemtuzumab, and while the review is ongoing the use of alemtuzumab is restricted.
15/04/2019 the EMA review and restriction was highlighted to the lead multiple sclerosis clinicians and linked to the formulary entry.

6.2. COST COMPARISON CHARTS

The Group discussed the potential to host cost comparison charts on the formulary website.

It was confirmed that the charts are produced by the Formulary Team and would be updated every 12 to 18 months.

The Group agreed that the comparisons could be useful, ideally they should be hosted in the relevant section on the formulary, and could highlight formulary medicines.

7. OTHER BUSINESS

7.1. AMGEVITA® ▼ - HIDRADENITIS SUPPURATIVA (PAEDIATRICS)

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

The Group considered the summary of the paediatric licence extensions for Amgevita® ▼, hidradenitis suppurativa (HS) and uveitis.

The Group noted:
- adalimumab, as the reference product Humira®, is already included on the formulary for HS in adolescents aged 12 years to < 18 years of age
- the paediatric HS indication for Amgevita® ▼ is in line with the current SMC advice for Humira®
- the use of adalimumab in uveitis, adults and adolescents, will be summarised for a future meeting **Ophth**

The Group supported the restricted local need for biosimilar adalimumab 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.

The Group accepted the restricted local need for the paediatric licence extension of Amgevita® for HS in adolescents aged 12 years to < 18 years of age without the need for a full submission.

SBAR – Amgevita® ▼ (adalimumab) 40mg prefilled pen and 20mg, 40mg prefilled syringe is routinely available in line with national guidance (SMC 1243/17).
Indication under review: treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adolescents (aged 12 years to <18 years) with an

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inadequate response to conventional systemic HS therapy.
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 conditions for which Amgevita® ▼ is indicated.
Patients should be given the Patient Reminder Card. **FTeam**

Biological medicines, including biosimlar 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.

7.2. 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.

The Group noted that:
- the licensed product is available as the same concentration and size of ampoule as the current unlicensed product (100micrograms/mL; 0.5mL ampoule)
- the licensed indications are wider than the current formulary acceptance
- the SMC has confirmed that this product is outwith SMC remit
- there is a potential that iloprost is being used for lower limb severe chronic ischaemia
- there is a query with the services regarding the current use of iloprost

The Formulary Group accepted that there is a local need for iloprost but requested confirmation of the indications that iloprost is current used for locally, and if use is in line with the indications for the licensed product. **FD**

7.3. FSRH - CHC GUIDANCE CHANGES – IMPLICATIONS

Ms Doney reported that the Faculty of Sexual and Reproductive Healthcare (FSRH) has recently reviewed its recommendations for combined hormonal contraception (CHC).

The FSRH highlights that:
- there is no health benefit from the seven-day hormone-free interval
- women can safely take no or fewer hormone-free intervals
- compliance with CHC is often not ideal, and the riskiest time to miss doses is at the beginning and the end of a hormone-free interval
- if a hormone-free interval is taken, shortening it to four days could potentially reduce the risk of pregnancy if pills, patches or rings are missed
- at the first consultation, many women can safely be prescribed a one year supply of CHC instead of the current three month supply

Ms Doney confirmed that the local sexual and reproductive health specialists are supportive of the FSRH advice, and that the Group generally supports recommendations from the FSRH.

There was not general support for prescribing a one-year supply of CHC at the first consultation.
The Group supported the recommendations for 'cycling' or a reduced pill-free interval, noting that 'cycling' was not a new concept.

The Group accepted the recommendations of the expert committee, FSRH, noting that the changes had the potential to increase prescribing costs. Ms Doney will highlight the potential increased costs to the Primary Care Prescribing Group (PCPG). **FD**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2014 - TOCILIZUMAB 162MG PRE-FILLED PEN/SYRINGE (GIANT CELL ARTERITIS)

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

The Group considered the request for tocilizumab for the treatment of Giant Cell Arteritis

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(GCA) in adult patients.

The Group noted:

- tocilizumab:
  - is the first biologic agent licensed for GCA
  - is given as a 162mg subcutaneous injection once every week in combination with a tapering course of glucocorticoids, and patients will complete 12 months of treatment before reassessment
  - can be used alone following discontinuation of glucocorticoids, but monotherapy should not be used for the treatment of acute relapses
  - [for this indication] meets SMC orphan equivalent criteria, and was accepted for restricted use in NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers that can be applied when encountering high cost-effectiveness ratios
  - would be supplied under a Homecare arrangement
  - [for this indication] is potentially steroid-sparing and has been requested for individual patients
- licensing is based on small patient numbers and short-term data
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of tocilizumab
- the SMC advice is subject to a 12-month clinical stopping rule, and the longer treatment is used the less cost-effective treatment becomes
- the SmPC states that '*treatment beyond 52 weeks should be guided by disease activity, physician discretion, and patient choice*'
- the service highlighted the lack of long-term data makes it difficult to ascertain if patients completing 12 months of treatment are likely to require prolonged treatment duration or not
- that there is a risk of rebound on stopping tocilizumab
- [for most cases in the management of GCA] when using steroids clinicians can use the C-reactive protein (CRP) level to judge if the disease is burning out, however the use of tocilizumab will negate this effect
- the high cost of treatment, and that if treatment is continued beyond 12-months costs will be cumulative
- GCA is specific to cranial arteries, it is a medium vessel vasculitis but can effect large vessels
- other biologic agents are used for other vasculitis patients, there may be the potential for use [of tocilizumab] to extend into other vasculitis patients (other large and medium vessel diseases)
- any monitoring requirements would be the responsibility of the managed service

The Group noted the lack of long-term trial data and was unclear about the ability to apply the SMC restriction limiting treatment to 12 months. The Group considered there is risk that the use of tocilizumab could extend into other large or medium vessel vasculitis.

The Group accepted the restricted local need for tocilizumab in the treatment of GCA as outlined in SMC 2014. Acceptance is subject to presentation of audit data in the next 12-18 months, data to include indication and number of patients treated, numbers stopped and how long people remained on treatment. **Rheu**

SMC 2014 - Tocilizumab 162mg solution for injection in pre-filled syringe and pre-filled pen (RoActemra®) is routinely available in line with national guidance (SMC 2014).
Indication under review: the treatment of Giant Cell Arteritis (GCA) in adult patients.
Restriction: treatment with tocilizumab is subject to a 12-month clinical stopping rule.
A phase III study of patients with recently diagnosed or relapsed GCA reported superiority of tocilizumab plus 26-week glucocorticosteroid taper over placebo plus 26-week glucocorticosteroid taper for obtaining a sustained glucocorticosteroid-free remission of GCA at week 52.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tocilizumab and is contingent upon the

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continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of GCA. All patients treated with tocilizumab should be given the Patient Alert Card. **FTeam**

8.2. FG1SMC 2116 - TOFACITINIB (PSORIATIC ARTHRITIS)

Mrs Harper declared a non-personal, non-specific interest in Pfizer and took part in the discussion and decision-making.

The Group considered the submission for tofacitinib, as outlined in SMC 2116, as an additional treatment option for adults with active psoriatic arthritis.

The Group noted:
- tofacitinib:
  - is a Janus Kinase (JAK) inhibitor licensed for use in psoriatic arthritis at a dose of 5mg twice daily
  - is an oral medication used in combination with methotrexate, it is not licensed as monotherapy for this indication
  - is already included on the formulary for rheumatoid arthritis (RA), but it can be used as monotherapy for RA
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of tofacitinib
- numbers may be small initially but could increase with time
- that a Homecare arrangement may be available for tofacitinib
- apart from lipid monitoring the blood monitoring for patients on methotrexate and tofacitinib would be in line with the current methotrexate shared care arrangements
- the SmPC states that if a patient develops a serious infection treatment should be interrupted until the infection is controlled, and dose interruption or permanent discontinuation is dependent on the severity of laboratory abnormalities

Ms Doney reported that the Rheumatology Service has confirmed that it will take responsibility for lipid monitoring.

Ms Doney will confirm the Homecare offering for tofacitinib in the management of psoriatic arthritis. **FD**

The Group expressed concern that if treatment needs to be interrupted both drugs should be stopped, but the Primary Care prescriber may not be aware that people are also receiving tofacitinib from hospital/via a homecare arrangement.

Ms Davie reported that there is work currently ongoing regarding a system to provide Primary Care with details of medicines supplied by the managed service (including homecare arrangements).

The Group accepted that the issue is wider than just this drug/regimen and there is work ongoing to consider how this risk could be managed. However, the Group requested that the service ensures that colleagues in Primary Care are fully aware of:
- the initiation of tofacitinib, and that it is part of a treatment regimen - methotrexate plus tofacitinib
- the split supply of medicines and monitoring requirements/arrangements
- any special precautions that they should be aware of, e.g. opportunistic infection risk

The Group accepted the restricted local need for tofacitinib 5mg tablets used in combination with methotrexate for the treatment of active psoriatic arthritis, as outlined in SMC 2116.

SMC 2116 - Tofacitinib 5mg film-coated tablets (Xeljanz®) ▼ is routinely available in line with national guidance (SMC 2116).

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	Indication under review: in combination with methotrexate for the treatment of active psoriatic arthritis in adult patients whose disease has not responded adequately to at least two conventional disease-modifying antirheumatic drugs (DMARDs), given either alone or in combination. **Two phase III studies demonstrated superiority of tofacitinib when compared with placebo in reducing signs and symptoms of psoriatic arthritis in patients who had not previously received a TNF inhibitor medication and in those with an inadequate response or intolerance to tumour necrosis factor inhibitors.** **This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tofacitinib 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 supervised by specialist physicians experienced in the diagnosis and treatment of psoriatic arthritis.**	**FTeam**

8.3. FG1SMC 2122 - TOFACITINIB (ULCERATIVE COLITIS)

Mrs Harper declared a non-personal, non-specific interest in Pfizer and took part in the discussion and decision-making.

The Group considered the submission for tofacitinib, as outlined in SMC 2122, as an additional treatment option for adults with moderately to severely active ulcerative colitis.

The Group noted:

- tofacitinib:
  - [for ulcerative colitis] the recommended dose is 10mg twice daily for 8 weeks for induction and 5mg twice daily for maintenance. However, for some patients the induction dose (10mg twice daily) can be extended to 16 weeks, and considered for maintenance in order to maintain therapeutic benefit.
  - [for ulcerative colitis] could be used as monotherapy or prescribed in conjunction with glucocorticoids
  - should not be used in combination with azathioprine. [The tofacitinib SmPC states that "*tofacitinib has not been studied and its use should be avoided in combination with biologics such as TNF antagonists, interleukin (IL)-1R antagonists, IL-6R antagonists, anti-CD20 monoclonal antibodies, IL-17 antagonists, IL-12/IL-23 antagonists, anti-integrins, selective co-stimulation modulators and potent immunosuppressants such as azathioprine, 6-mercaptopurine, ciclosporine and tacrolimus because of the possibility of increased immunosuppression and increased risk of infection*"].
  - [for ulcerative colitis] would provide an oral treatment option compared to the current biologic agents that are given as intravenous infusion or subcutaneous injection
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of tofacitinib
- people will stay on treatment for as long as they benefit
- the estimate of patient numbers is significantly higher than the expected use in psoriatic arthritis
- patient numbers would be incremental and the effect on budget would be cumulative
- there is a possible safety signal with use of the higher dose of tofacitinib for RA [an increased risk of pulmonary embolism and overall mortality has been seen in a study with tofacitinib 10mg twice daily in RA]
- the service has confirmed that blood monitoring will remain the responsibility of the Department of Digestive Disorders

Ms Doney reported that the service has confirmed that tofacitinib will not be used in combination with azathioprine.

Ms Doney will confirm if homecare will be the supply route of tofacitinib in the management of ulcerative colitis. **FD**

The Group reiterated its concern that Primary Care prescribers may not be aware that people are receiving tofacitinib (or other immunosuppressive agents) from hospital/via a homecare arrangement, and supported initiatives that close this information gap.

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The Group accepted the restricted local need for tofacitinib 5mg and 10mg tablets for the treatment of adult patients with moderately to severely active ulcerative colitis, as outlined in SMC 2122.

As patients may present to Primary Care showing signs of an adverse drug reaction to tofacitinib, the Group requested that the service ensures that colleagues in Primary Care are fully aware of the initiation and supply of tofacitinib, that blood monitoring will remain the responsibility of the Department of Digestive Disorders, and any special precautions that they should be aware of, e.g. opportunistic infection risk. **DpDD**

SMC 2122 - Tofacitinib 5mg, 10mg film-coated tablets (Xeljanz®)▼ is routinely available in line with national guidance (SMC 2122).
Indication under review: for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.
In phase III studies, tofacitinib was superior to placebo in achieving and sustaining remission in adult patients with moderately to severely active ulcerative colitis who had treatment failure with, or were intolerant to, a conventional or biologic medicine.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tofacitinib 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 supervised by specialist physicians experienced in the diagnosis and treatment of ulcerative colitis. **FTeam**

8.4. SMC 2142 - DASATINIB (PAEDIATRIC EXTENSION - CHRONIC MYELOGENOUS LEUKAEMIA)

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

The Group discussed the abbreviated SMC advice for the paediatric licence extension of dasatinib.

The Group noted:
- dasatinib is already included on the formulary for use in adults
- the licence extension applies to paediatric patients aged 1 year and older who are newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia in chronic phase (Ph+ CML-CP) or Ph+ CML-CP resistant or intolerant to prior therapy including imatinib
- CML in children is rare, and patient numbers are expected to be very low
- treatment of leukaemia is protocol driven
- the paediatric service supports formulary inclusion
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of dasatinib

The Group accepted the restricted local need for dasatinib for the treatment of paediatric patients, aged 1 year and older, with newly diagnosed Ph+ CML-CP, or Ph+ CML-CP resistant or intolerant to prior therapy including imatinib, without the need for a full submission.

SMC 2142 - Dasatinib 20mg, 50mg, 80mg, 100mg, 140 mg film-coated tablets (Sprycel®) is routinely available in line with national guidance (SMC 2142).
Indication under review: for the treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia in chronic phase (Ph+ CML-CP) or Ph+ CML-CP resistant or intolerant to prior therapy including imatinib.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of dasatinib and is contingent upon the continuing availability of the patient access scheme 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. Therapy should be initiated by a physician experienced in the diagnosis and treatment of patients with leukaemia. **FTeam**

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8.5. SMC 2139 - MEPOLIZUMAB (PAEDIATRIC EXTENSION - ASTHMA)

Dr Fitton declared a person, specific interest in GlaxoSmithKline (GSK) and did not take part in the discussion or decision-making.

Mrs Harper declared a non-person, non-specific interest in GSK and took part in the discussion and decision-making.

The Group discussed the abbreviated SMC advice for mepolizumab (SMC 2139) that extends use to include children and adolescents aged 6 years to < 18 years.

The Group noted:
- mepolizumab is already included on the formulary for the same restricted indication for adults aged 18 years and older (SMC 1149/16)
- the level of eosinophil elevation noted in the SMC advice is not very high
- local use is expected to be low
- making mepolizumab available for paediatric patients aged 6 years to < 18 years will bring use in line with acceptance for adults aged 18 years and older

Ms Doney will request an estimate of patient numbers to allow the financial implications to be considered by colleagues in finance. **FD**

The Group accepted the restricted local need for the paediatric licence extension [aged 6 to <18 years] for mepolizumab as outlined in SMC 2139, without the need for a full submission.

SMC 2139 – Mepolizumab 100mg powder for solution for injection (Nucala®) ▼ is routinely available in line with national guidance (SMC 2139).
Indication under review: as an add-on treatment for severe refractory eosinophilic asthma in children and adolescents aged 6 years to <18 years.
Restriction: patients who have eosinophils of at least 150 cells per microlitre (0.15 x 10^9/L) at initiation of treatment and have had at least four asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of mepolizumab 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. Mepolizumab should be prescribed by physicians experienced in the diagnosis and treatment of severe refractory eosinophilic asthma. **FTeam**

8.6. SMC 2148 - BLINATUMOMAB (PAEDIATRIC EXTENSION - ACUTE LYMPHOBLASTIC LEUKAEMIA)

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

The Group considered the abbreviated SMC advice that extends the use of blinatumomab to paediatric patients from 1 year of age with Philadelphia chromosome negative CD19 positive B-cell precursor acute lymphoblastic leukaemia (ALL).

The Group noted:
- blinatumomab is included on the formulary for the treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor ALL (SMC 1145/16)
- the estimate of patient numbers is low but the cost of the medicine is high
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of blinatumomab

The Group accepted the restricted local need for the paediatric licence extension for blinatumomab, as outlined in SMC 2148, without the need for a full submission.

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SMC 2148 – Blinatumomab is routinely available in line with national guidance (SMC 2148). ▼
Indication under review: as monotherapy for the treatment of paediatric patients aged 1 year to < 18 years with Philadelphia chromosome negative CD19 positive B-cell precursor acute lymphoblastic leukaemia (ALL) which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic hematopoietic stem cell transplantation.
SMC accepted blinatumomab for use in adults following a submission under the end of life and ultra-orphan process.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of blinatumomab 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 under the direction of and supervised by physicians experienced in the treatment of haematological malignancies. **FTeam**

8.7. SMC 2146 - RUFINAMIDE (PAEDIATRIC EXTENSION - SEIZURES ASSOCIATED WITH LENNOX-GASTAUT SYNDROME)

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

The Group considered the abbreviated SMC advice that extends the use of rufinamide to include children aged 1 to < 4 years.

The Group noted:
- rufinamide:
  - is licensed as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome, and the SMC restricted use to patients who have failed treatment with or are intolerant of other antiepileptic drugs
  - is not used as monotherapy
  - should be initiated by a physician specialised in paediatrics or neurology with experience in the treatment of epilepsy
- Lennox-Gastaut syndrome is a severely debilitating form of generalised paediatric epilepsy
- local use of rufinamide is low

The Group accepted the restricted local need for the paediatric licence extension of rufinamide to include children aged 1 to < 4 years, without the need for a full submission.

SMC 2146 - Rufinamide 40mg/mL oral suspension and 100mg, 200mg, 400mg tablets (Inovelon®) is routinely available in line with national guidance (SMC 2146).
Indication under review: as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 1 years to < 4 years.
Restriction: to use in patients who have failed treatment with or are intolerant of other antiepileptic drugs.
Rufinamide has previously been accepted for restricted use in adults and children aged 4 years and older. The licence has been extended to include children aged 1 year to < 4 years.
It was classified 1b- available for restricted use under specialist supervision and 8c - treatment to be initiated in hospital prior to handover. Treatment with rufinamide should be initiated by a physician specialised in paediatrics or neurology with experience in the treatment of epilepsy. **FTeam**

8.8. SMC 1256/17 - CILODEX® (CIPROFLOXACIN PLUS DEXAMETHASONE EAR DROPS) - (ACUTE OTITIS MEDIA IN PATIENTS WITH TYMPANOSTOMY TUBES AND ACUTE OTITIS EXTERNA)

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

The Group considered the request for a combination ciprofloxacin (0.3%) and dexamethasone (0.1%) ear drop preparation (Cilodex®).

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The Group noted:
- Cilodex®:
  - is licensed for the treatment of adults and children for:
    - acute otitis media in patients with tympanostomy tubes (6 months and older) and
    - acute otitis externa (AOE) (1 year and older)
  - provides a licensed combination corticosteroid and anti-infective ear drop preparation. Ciprofloxacin is available as a licensed single agent ear drop (ciprofloxacin 2mg/mL, Cetraxal® ear drops), and single agent dexamethasone is not available as a licensed ear drop preparation.
- over the past few years there have been supply issues with some ear drops including corticosteroid/anti-infective combination products
- the availability of another licensed product would be positive for prescribers
- depending on which product(s) are replaced overall costs may increase or decrease
- generic prescribing is supported as there is a risk that patients receive duplicate therapy if medicines are prescribed by brand names

The Group requested that the service prescribe by generic names, specifying the component parts, rather than prescribing by brand name. **ENT**

The Group accepted the restricted local need for a ciprofloxacin plus dexamethasone ear drops 3mg/mL / 1mg/mL (Cilodex®) as licensed, use will be in line with local prescribing guidance.

SBAR - Ciprofloxacin and dexamethasone ear drops 3mg/mL / 1mg/mL (Cilodex®) is routinely available in line with local guidance.
Indications under review: for the treatment of the following infections in adults and children:
- **acute otitis media in patients with tympanostomy tubes (AOMT)**
- **acute otitis externa (AOE)**

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**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED APRIL 2019

The Group noted the SMC provisional advice issued April 2019.

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

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED APRIL 2019

The Group noted the SMC advice published April 2019.

The following SMC accepted medicines have not been processed within 60-day timescale:
- SMC 2132 certolizumab pegol (Cimzia®)
- SMC 2134 erenumab (Aimovig®) ▼
- SMC 2138 lenvatinib 4mg hard capsules (Lenvima®) ▼
- SMC 2152 testosterone 20mg/g transdermal gel (Testavan®)

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

11. GENERAL INFORMATION FROM SMC APRIL 2019 - NONE

12. DOCUMENTS FOR INFORMATION

Items 12.1 (MHRA Drug Safety Update March 2019) and 12.2 (Antimicrobial Management Team Meeting - minute January 2019) were noted.

ITEM	SUBJECT	ACTION

13. AOCB

BEVACIZUMAB FOR WET AMD

The Group discussed the High Court decision that found in favour for the use of bevacizumab (Avastin®) in the treatment of wet age-related macular degeneration (wet AMD).

In view of the clarification from the General Medical Council (GMC) and the significant cost differential, the Chairman will write to the Director of Pharmacy to request an update on the local and national positions regarding this High Court decision. **JMcL**

Ms Doney will confirm the Royal College of Ophthalmologists position regarding the use of bevacizumab in the treatment of wet AMD. **FD**

SINGLE NATIONAL FORMULARY

The Chairman requested an update on the status of the Single National Formulary (SNF). **FD**

NORTH OF SCOTLAND CANCER NETWORK

The Chairman requested an update on the proposal that the North of Scotland Cancer Network (NOSCAN) would undertake reviews of cancer medicines for the North of Scotland Health Boards. **FD**

It was reported that NOSCAN has been 'rebranded' and the relevant body is now the North Cancer Alliance (NCA). Official notification of the change is awaited, however there is a public facing NCA website.

DATE OF NEXT MEETING

Tuesday 21 May 2019 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE _____ **DATE** **21 May 2019**