NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 15 May 2018 at 14:30 in the Seminar Room, David Anderson Building

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

IN ATTENDANCE
Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team for item 3 (until item 7.4).
Mrs Sally-Ann Chadha, Secretary/Administrator, Medicines Management.

ITEM	SUBJECT	ACTION
	The Chairman opened the meeting, welcomed members and noted that a quorum was present.	
1.	**APOLOGIES**	
	Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 17 APRIL 2018**	
	The draft minute was issued the day before the meeting so members were given to the end of the week to return any comments to Ms Doney. Members ratified the minute subject to any changes required due to comments received.	**All**
	The final minute will be in the public domain within 21 days of approval.	**FD**
3.	**PRESENTATION - NETFORMULARY**	
	Ms Dawn Bruce, Specialist Pharmacy Technician provided the Group with a short demonstration of the new formulary website. Ms Doney highlighted a few sections and areas of interest. Ms Doney advised that a link would be sent to members to test the site and provide feedback. She requested members consider which links should be provided on the homepage. Ms Doney confirmed that netFormulary site is planned for launch June 2018.	
4.	**MATTERS ARISING**	
	4.1. ACTION LOG	
	The Chairman reviewed the Action log with the Group to clarify the status of items that were not included on the agenda.	
	NALOXONE NASAL SPRAYS Awaiting feedback from the Specialist Pharmacists in Substance Misuse. This item will remain on the Action log.	
	BUCCAL MIDAZOLAM Ms Doney confirmed that the Children's Epilepsy Specialist Nurse has just updated the letter for prescribers, and it will be finalised and issued to prescribers in the next few weeks. This item will be removed from the Action log.	**FD**
	LOCAL PAIN LADDER ADVICE The Chairman advised that links to pain ladders would be sent by email. This item will be removed from the Action log.	**FD**
5.	**FORMULARY GROUP DECISIONS APRIL 2018 - PUBLISHED 01/05/2018**	
	The Group ratified the advice as published.	

6. NETFORMULARY/FORMULARY REVIEW

6.1. LEVONORGESTREL INTRAUTERINE DELIVERY SYSTEMS FOR CONTRACEPTION

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

The Group considered the SBAR comparing the current levonorgestrel-containing intrauterine delivery systems.

Ms Doney provided members with a brief overview of the different products:

- Jaydess® and Kyleena® are direct comparators, both are only licensed for contraception but Kyleena® contains a higher dose of levonorgestrel and has an additional two years cover (licensed up to 5 years) at a small additional cost (<£7)
- the specialist service has confirmed that there is a local need for Kyleena®, and whilst there is an expectation that Kyleena® may replace Jaydess® the service would prefer both products remain on formulary. The use/prescribing of Jaydess® will be reviewed in approximately one year.
- Levosert® and Mirena® are similar, both contain 52mg levonorgestrel per device, but there are differences in licensing and the inserter
- Levosert® is licensed for contraception and heavy menstrual bleeding. February 2018 both licences increased from 3 years to 4 years, and if accepted the next extension to licence (i.e. 5 year licence) is likely to be available early next year.
- Mirena® is licensed for contraception, heavy menstrual bleeding, and protection from endometrial hyperplasia during oestrogen replacement therapy (used for 5 years - all indications)
- Levosert® is currently non-formulary. When it first came to market, it was not preferred [to Mirena®] because it only had a 3-year licence and it used an older style inserter.
- it is not known how many women retain the Mirena® IUS for 5 years. The Sexual Health Service will investigate the possibility of auditing local data to provide this information.

A member noted the low use of Jaydess®.

The Group discussed the different devices, the possible implications of a failed insertion and the risk of uterine perforation with intrauterine systems.
Taking all points into consideration the Group supported the local need for Kyleena® with Jaydess® remaining on the formulary and prescribing reviewed in approximately one year. **SHS**

The concerns regarding the Levosert® inserter remain and the Group felt there was insufficient information to include Levosert® on the formulary at this time but it would support the use of Levosert® by the Specialist Service if required. The formulary position will be reviewed next year if Levosert® receives a 5-year licence. **SHS/ FTeam**

SMC 1299/18 - Kyleena® (levonorgestrel 19.5mg intrauterine delivery system) is routinely available in line with national guidance (1299/18).
Indication under review: contraception for up to 5 years.
A phase III, open-label, randomised study confirmed the contraceptive efficacy of levonorgestrel 19.5mg intrauterine delivery system according to the Pearl Index. It was classified 1a - available for general use and 8e - treatment may be initiated in either hospital or community. Kyleena® should only be inserted by physicians/healthcare professionals who are experienced in IUS insertions and/or have undergone training on the Kyleena® insertion procedure. **FTeam**

6.2. CONTRACEPTIVES – COMBINED ORAL CONTRACEPTIVES

Ms Doney reported that the Formulary Team has reviewed the costs of the currently available oral contraceptives (OCs).

Ms Doney confirmed that:

- the current formulary choice OCs are the Consilient Health Ltd branded-generic range
- new product ranges have come to market, for example Morningside, and some of the products cost less than the equivalent Consilient products, however Consilient has a more comprehensive product range
- the Sexual Health Service supports the continued use of the Consilient range of OCs

Members reported that a significant amount of work has been done to familiarise prescribers with the Consilient range of OCs, and since adoption to formulary there have been no supply problems with the Consilient range.

To ensure consistency and avoid confusion the Group endorsed the continued use of the Consilient Health Ltd branded-generic range of OCs. **FTeam**

6.3. SIGN 155 – PHARMACOLOGICAL MANAGEMENT OF MIGRAINE

The Group considered the SBAR outlining changes required to the formulary in light of the recommendations of SIGN 155 – Pharmacological Management of Migraine.

Ms Doney confirmed that:

- the Formulary Team do not usually review SIGN guidelines, however, as SIGN 155 only deals with the pharmacological management of migraine the key recommendations will directly affect formulary choices and it was appropriate to undertake a review
- for acute management, there is a marginal change in the upper dose of ibuprofen, decreasing from 800mg to 600mg - the formulary will be updated to reflect this
- gabapentin is no longer considered a prophylactic treatment - the formulary will be updated to reflect this
- for females of child-bearing potential the recommended use of sodium valproate will reflect the latest guidance issued by the Medicines and Healthcare products Regulatory Agency
- combination products are not included in the SIGN guidelines, and the use of combination products is not supported by the Headache Service. This advice will be highlighted on the formulary and the Headache Service will provide advice for prescribers/Community Pharmacy.
- tolfenamic acid, although licensed for acute migraine, is non-formulary and this will be highlighted
- pizotifen as the brand Sanomigran® was discontinued in 2014, and the cost of pizotifen (all formulations) has increased over time. Pizotifen tablets are available as licensed generic products, but pizotifen 250micrograms/5mL oral solution is now only available as an unlicensed product that costs at least 75 times more than the previously licensed product Sanomigran® liquid.

The Group discussed the continued use of pizotifen noting that the SIGN guideline reports - "*There is insufficient evidence to support a recommendation, but it is a well-established therapy which is widely used*". The Group queried if pizotifen should remain on the formulary, but was mindful that pizotifen (500microgram tablet) is one of the few medicines licensed for migraine prevention in paediatric patients.

The Group accepted the recommended changes required to bring the formulary in line with SIGN 155, and recommendations to highlight non-formulary products.

The Group agreed that:

- **the formulary should be updated to reflect the recommendations in SIGN 155, and gabapentin is no longer recommended as a prophylactic treatment for patients with episodic or chronic migraine** **FTeam**
- **pizotifen 250micrograms/5mL oral solution should be noted as non-formulary** **FTeam**
- **the Headache Service should provide prescribing advice/prescribing guidelines for prescribers in Primary Care to support the use of topiramate, and highlight medicines that are not preferred, e.g. combination analgesic products** **CD/DW**
- **ScriptSwitch should be used to highlight the non-formulary status of particular non-triptan medicines, e.g. Migraleve®, Migramax®, Migril®, tolfenamic acid** **AD/FD**

6.4. EMOLLIENTS

Ms Doney confirmed that the Formulary Team has reviewed the cost of emollients with a view to bringing information to the June meeting.

Ms Doney reported that:

- new product ranges that are comparable to established brands are available, and the new ranges are included in the Scottish Drug Tariff
- the review compares similar products/formulations looking for a cost-minimisation

strategy
- an emollient ladder has been drafted, and will be passed to the specialist service for comment
- the use of bath additives is not supported and these products remain non-formulary **FTeam**

7. OTHER BUSINESS

7.1. SIGN 151- Management of stable angina

Ms Doney confirmed that the key recommendations do not affect pharmacological treatments but the guidance will be used as an opportunity to review the use of unlicensed preparations and medicines used off-label for the management of angina/refractory angina. **FTeam**

7.2. NIVOLUMAB

Ms Doney advised that nivolumab is now licensed with simpler fixed-dosing schedules [480mg every four weeks for two indications and 240mg every two weeks to replace weight-based dosing for all monotherapy indications]. This change to the Summary of Product Characteristics (SmPC) is out of remit for the SMC so was raised with the Aseptic and specialist services to consider the risk/benefit of changing the dosing schedules. Previously pembrolizumab would have been preferred to nivolumab because it had a longer dosing interval, three weeks versus two weeks. The services have confirmed that the new dosing schedules will be adopted. This change will not affect the current formulary advice but the costing for the new schedules will be included in any future submissions.

7.3. REVIEW OF BLOOD GLUCOSE TEST STRIPS

The Group considered the document outlining the Diabetic Managed Clinical Network (MCN) recommendations for the self-monitoring of blood glucose (SMBG) for Type 2 diabetes.

Ms Doney confirmed that the document and recommendations are confidential, that the MCN is responsible for implementation of the recommendations and the request for the Formulary Group to ratify the recommendations is just one step in the implementation process.
The Group highlighted the importance of engaging with the public/patients to support the use of the preferred meters and strips.

The Group supported the Diabetic Managed Clinical Network (MCN) recommendations for the SMBG for Type 2 diabetes, and ratified the preferred meters and strips choices for hosting on the formulary when the advice is publicly available. **FTeam**

7.4. GENERIC PRESCRIBING

The Group noted the information distributed by The Grampian Primary Care Prescribing Group regarding generic prescribing.

7.5. INFORMATION FOR PRESCRIBERS - XAGGITIN® XL

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

The Group authorised the draft document for publication. The document will be passed to the Grampian Primary Care Prescribing Group for consideration. **FD**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 1139/16 – TEDUGLUTIDE (SHORT BOWEL SYNDROME)

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

The Group considered the submission for teduglutide for the treatment of patients aged one year and above with short bowel syndrome (SBS).

The Group noted:
- that SBS is a rare condition and patient numbers are expected to be very low
- teduglutide:
  - is a glucagon-like-peptide-2 analogue which is the only medicine licensed for the treatment of SBS

  - has been designated an orphan medicine for the treatment of SBS by the European Medicines Agency (EMA)
  - meets SMC ultra-orphan criteria and was accepted for restricted use in NHS Scotland following the output from the PACE process and application of the appropriate SMC modifiers
  - might be supplied under a Homecare arrangement
  - monitoring is the responsibility of the managed service
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of teduglutide

The Group accepted the restricted local need for teduglutide injection for the treatment of short bowel syndrome as outlined in SMC 1139/16. Treatment will be restricted to initiation in paediatric patients (aged 1 to 17 years).

SMC 1139/16 - Teduglutide 5mg, 1.25mg vials of powder and solvent for solution for injection (Revestive®) ▼ is routinely available in line with national guidance (SMC 1139/16).
Indication under review: for the treatment of patients aged one year and above with short bowel syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery.
Restriction: initiation in paediatric patients (aged 1 to 17 years).
Results of one phase III randomised study in adults demonstrated that significantly more patients treated with teduglutide compared with placebo achieved at least a 20% reduction in parenteral support at weeks 20 and 24. A 12-week open-label, non-randomised study in paediatric patients also found parenteral support was reduced with teduglutide compared with standard of care.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of teduglutide 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 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 under the supervision of a medical professional with experience in the treatment of SBS. **FTeam**

8.2. FG1 406/18 – DROPERIDOL (POST-OPERATIVE VOMITING IN CHILDREN)

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

The Group considered the request from Paediatric Anaesthesia to include droperidol on the formulary for the prevention and treatment of post-operative vomiting in children.

The Group noted that:
- droperidol (2.5mg/mL) injection:
  - was previously voluntarily withdrawn by the manufacturer (2001) due to safety concerns related to QT interval prolongation. In 2009 it was reintroduced and the new preparation is considered outwith remit for SMC.
  - prolongs the QT interval, and is contraindicated in patients with known QT syndrome
- use is in line with The Association of Paediatric Anaesthetists of Great Britain and Ireland (APAGBI) guideline
- the paediatric service plans to stock droperidol in Royal Aberdeen Children's Hospital (RACH) Theatres and recovery area and will be prescribed under the guidance of a Paediatric Anaesthetist
- in 2010 a request for use in the adult service was rejected

Members discussed the potential for use of droperidol slipping into the adult service. Ms Doney will check with the adult service if there is a local need for droperidol. If needed a separate specific request will be required. **FD**

The Group supported the restricted use of droperidol for the prevention and treatment of post-operative vomiting in children and adolescents in line with the APAGBI guidelines on the prevention of post-operative vomiting.

Droperidol 2.5mg/mL solution for injection is routinely available in line with local guidance.
Indication under review:
- **in combination with ondansetron for the prophylaxis of post-operative vomiting in children and adolescents (2 to <18years) at high risk of post-operative vomiting who are unable to take dexamethasone**
- **for the treatment of established post-operative vomiting in children and adolescents (2 to <18 years), as a second drug, after ondansetron**

It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Droperidol should only be prescribed under the supervision/guidance of a paediatric anaesthetist. Use will be limited to RACH Theatres/recovery area. **FTeam**

8.3. SBAR - 5-AMINOLAEVULINIC ACID (AMELUZ®) (BASAL CELL CARCINOMA)

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

The Group considered the SBAR regarding the use of the aminolaevulinic acid products Metvix® and Ameluz®. Metvix® is the current formulary product, used in specialist centres (in combination with photodynamic therapy) to treat actinic keratoses, Bowen's disease, and basal cell carcinoma (when other treatments are inadequate or unsuitable).

The Group noted that:
- Ameluz®:
  - is currently non-formulary for another indication [SMC 811/12, actinic keratoses]
  - has dropped in price since launch [reduced from £184 to £170 per 2g pack]
  - now costs marginally less than Metvix® [£1.50 per pack]
  - has fewer licensed indications than Metvix®

The Group supported the current non-formulary status for Ameluz® accepting that this position will be reviewed if requested by the specialist service.

SMC 1260/17 - 5-aminolaevulinic acid (as hydrochloride) 78mg/g gel (Ameluz®) is not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time.
Indication under review: treatment of superficial and/or nodular basal cell carcinoma (BCC) unsuitable for surgical treatment due to possible treatment-related morbidity and / or poor cosmetic outcome in adults.
In a phase III study of patients with BCC, up to two cycles of photodynamic therapy (PDT) with 5 aminolaevulinic acid gel was non-inferior to PDT with an alternative photosensitising agent for the primary endpoint, complete clearance, defined as clearance of all treated lesions, assessed visually at 12 weeks after the last PDT.
Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time. **FTeam**

8.4. FG1SMC 1315/18 - AVELUMAB (METASTATIC MERKEL CELL CARCINOMA)

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

The Group reviewed the submission for avelumab for the treatment of adult patients with metastatic Merkel cell carcinoma.

The Group noted:
- that metastatic Merkel cell carcinoma is a very rare cutaneous neuroendocrine tumour and patient numbers are expected to be very low
- avelumab:
  - is the first medicine licensed for the treatment of metastatic Merkel cell carcinoma
  - (for this indication) meets SMC end of life and ultra-orphan 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
- that treatment should continue until disease progression or unacceptable toxicity and costs will depend on the number of cycles given
- there are no patients waiting for treatment, however inclusion on the formulary would

prevent delay in treatment should a need arise

The Group accepted the restricted local need for avelumab infusion for adult patients with metastatic Merkel cell carcinoma as outlined in SMC 1315/18.

SMC 1315/18 - Avelumab 20mg/mL concentrate for solution for infusion (Bavencio®) ▼ is routinely available in line with national guidance (SMC 1315/18).
Indication under review: as monotherapy for the treatment of adult patients with metastatic Merkel cell carcinoma (mMCC).
An uncontrolled phase II study demonstrated that treatment with avelumab for patients with mMCC who had received prior chemotherapy produced improvements in objective response rate, duration of response and overall survival compared with historical chemotherapy controls from a retrospective cohort study.
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 should be initiated and supervised by a physician experienced in the treatment of cancer. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED MAY 2018

The Group noted the SMC provisional advice issued May 2018.

If the non-submission statement for eslicarbazepine acetate (Zebinix®) SMC 2090 is published next month this medicine will not be included on the Grampian Joint Formulary for the indication in question. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED MAY 2018

The Group noted the SMC advice published May 2018.

Following publication of the non-submission statements, for brentuximab vedotin (Adcetris®) ▼ SMC 2085 and naltrexone/bupropion (Mysimba®) ▼ SMC 2086, these medicines will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

The following SMC accepted medicines have not been processed within a 60-day timescale:
- SMC 1318/18 nusinersen (Spinraza®) ▼ (submission in progress)
- SMC 1316/18 regorafenib (Stivarga®) ▼ (submission in progress)
- SMC 1283/17 brodalumab (Kyntheum®) ▼

Local advice for these medicines and indications will be included in the May 2018 decisions as **'Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts'.** **FTeam**

SMC 1235/17 - SELEXIPAG (UPTRAVI®) ▼

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

The Group considered the SMC advice for selexipag a medicine licensed for the treatment of pulmonary arterial hypertension (PAH) in adult patients.

Ms Doney confirmed that:
- PAH medicines are generally not included on the formulary because these specialist medicines are supplied by the Scottish Vascular Centre
- the Scottish Vascular Centre has confirmed that selexipag will be included in its guidance and will be initiated, prescribed and supplied by specialists in the Scottish Pulmonary Vascular Unit

SMC 1235/17 - Selexipag 200microgram, 400microgram, 600microgram, 800microgram, 1,000microgram, 1,200microgram, 1,400microgram, 1,600microgram film-coated tablets (Uptravi®) ▼ is available from a specialist centre in another NHS Board. If local need identified treatment is initiated and prescribed by specialists in the Scottish Pulmonary Vascular Unit.
Indication under review: for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients, as combination therapy, for patients in WHO FC

III who are insufficiently controlled with an ERA and a PDE-5 inhibitor and who would be considered for treatment with inhaled iloprost.
Restriction: initiation and prescribing by specialists in the Scottish Pulmonary Vascular Unit.
In a phase III study of patients with PAH, selexipag was statistically significantly better than placebo as measured by a composite primary outcome of death or a complication related to PAH.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of selexipag 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.
Available from a specialist centre in another NHS Board. If a local need identified treatment will be initiated and prescribed by specialists in the Scottish Pulmonary Vascular Unit. Treatment should only be initiated and monitored by a physician experienced in the treatment of PAH. **FTeam**

SMC 1332/18 - ICATIBANT ACETATE (FIRAZYR®) – HAE PAEDIATRICS

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

The Group considered the abbreviated SMC advice for icatibant SMC 1332/18.

The Group noted:
- the abbreviated SMC advice considers the licence extension of icatibant acetate to include children and adolescents aged 2 to 18 years
- in 2012 icatibant acetate was included on the formulary for adults for this indication (18 years and older, SMC 476/08), and the indication for the new and previous SMC advice is consistent
- there are no paediatric patients waiting for treatment, however inclusion on the formulary would prevent delay in treatment should a need arise
- Dr Herriot has confirmed that paediatric patients' transition to the adult immunology service at 16 years, and although there are no patients requiring treatment at the moment he supports formulary inclusion in line with the extension to licence

The Group accepted the restricted local need for icatibant acetate (Firazyr®) for the symptomatic treatment of acute attacks of HAE in children and adolescents (aged 2 to 18 years) with C1-esterase-inhibitor deficiency without the need for a full submission.

SMC 1332/18 - Icatibant acetate 30mg solution for injection in pre-filled syringe (Firazyr®) is routinely available in line with national guidance (SMC 1332/18).
Indication under review: symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adolescents and children aged 2 years and older, with C1-esterase-inhibitor deficiency.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of icatibant and is contingent upon the continuing availability of the PAS in NHS Scotland. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. **FTeam**

11. GENERAL INFORMATION FROM SMC MAY 2018

The Chairman confirmed that Janssen-Cilag Ltd has discontinued commercial availability of simeprevir (Olysio®) and withdrawn the marketing authorisation. Simeprevir is no longer included in the national guidelines but is still noted on the Formulary.
The service is aware of the withdrawal and the formulary entry will be amended. **FTeam**

12. DOCUMENTS FOR INFORMATION

Item 12.1 (Drug Safety Update for April), 12.2 (CMO letter – Valproate contraindicated in women of childbearing potential unless there is a Pregnancy Prevention Programme) and 12.3 (Antimicrobial Management Team Meeting minute February 2018) were noted.

13. AOCB

STATINS

Ms Davie requested an update on the 'statin' algorithm.
Ms Doney confirmed that the feedback to simplify the algorithm is being taken forward and the consultation is ongoing. Updated information will come to a future meeting. **FD**

DATE OF NEXT MEETING

Tuesday 19 June 2018 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE _____ **DATE 19 June 2018**