NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 21 June 2016 at 14:30 in the Aspen Room, Forest Grove House, Aberdeen

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

PRESENTATION
Mrs Louise McKee, Oncology Pharmacist.

IN ATTENDANCE
Ms Kate Robertson, Secretary Formulary Team.

ITEM	SUBJECT	ACTION
	The Chairman opened the meeting and noted that a quorum was present. Due to technical issues at the start of the meeting several item were taken out of order.	
1.	**APOLOGIES**	
	The Chairman welcomed members and Mrs McKee to the meeting, apologies for absence were requested and noted.	**FD**
2.	**DRAFT MINUTE OF THE MEETING HELD 17 MAY 2016**	
	The Chairman confirmed that membership of the previous meeting did not meet a quorum and the Group ratified the decisions of the May meeting. The Group accepted the draft note of the meeting held 17 May 2016 as an accurate record of the meeting subject to minor typographical changes.	**FD**
	The corrected approved minute will be in the public domain within 21 days.	**FTeam**
5.	**FORMULARY GROUP DECISIONS MAY 2016 – PUBLISHED 03/05/2016**	
	The Group ratified the advice as published.	
6.	**CMO(2012)1 REPORTING FOR SCOTTISH MEDICINES CONSORTIUM (SMC) ADVICE - 2016/17**	
	It was confirmed that for the SMC accepted medicines published April to May 2016 the Formulary Group (FG) audit standard for CMO(2012)1 reporting was achieved for the following criteria: • Local decision on SMC accepted medicine published within 90 days: 7 of 7 - 100% • FG decision published within 14 days of the decision being reached: 7 of 7 - 100%	**FD**
12.	**DOCUMENTS FOR INFORMATION**	
	Items 12.1 (Drug Safety Update May 2016), 12.2 (Minutes of the Medicines Guidelines and Policies Group – April 2016), 12.3 (Formulary Group Meeting Dates 2017) and 12.4 (Medicines in Scotland: What's the right treatment for you? Information factsheet for patients and the public) were noted.	

ITEM	SUBJECT	ACTION

3. PRESENTATION/DISCUSSION - MANAGEMENT OF CANCER THERAPY INDUCED NAUSEA AND VOMITING

Mrs Louise McKee, Oncology Pharmacist, provided the Group with an update on the management of chemotherapy-induced nausea and vomiting in the context of national, regional and local antiemetic guidelines and SMC approvals.

Mrs McKee confirmed that:

- the Multinational Association of Supportive Care in Cancer (MASCC) in collaboration with the European Society for Medical Oncology (ESMO) published updated antiemetic guidelines in 2016
- the North of Scotland Cancer Network (NOSCAN) antiemetic policy is due to be updated November 2016, and this policy is based on the MASCC guidelines and SMC advice
- Akynzeo® ▼:
  - is a fixed dose combination oral capsule containing two antiemetics: netupitant, a selective neurokinin 1 (NK1) receptor antagonist, and palonosetron, a selective 5-hydroxytryptamine (serotonin) type 3 (5-HT3) receptor antagonist
  - provides a simple dosage regimen – one oral capsule taken once daily approximately one hour prior to the start of each chemotherapy cycle
  - provides a simpler dosing regimen for patients and a benefit to the aseptic dispensary (no need for labelled ondansetron for patients to take home)
- MASCC/ESMO recommend regimens containing NK1 and 5-HT3 receptor antagonists for the prevention of nausea and vomiting for highly emetogenic chemotherapy regimens, anthracycline plus cyclophosphamide based chemotherapy regimens, and carboplatin chemotherapy regimens
- palonosetron, as the single agent product, was accepted by SMC for moderately and highly emetogenic chemotherapy
- the service wishes to extend the use of NK1 and 5-HT3 receptor antagonists to antiemetic failure (in line with other areas in NHS Scotland)
- antiemetic failure is defined as - prolonged and distressing nausea, and/or two or more episodes of vomiting in 24 hours (Grade 2)
- in patients who experience antiemetic failure it is standard practice to step up to the next highest emetogenic class
- local audit data demonstrates nausea and vomiting is the most common reason for admission to Acute Medical Initial Assessment via the chemotherapy helpline number

The Chairman thanked Mrs McKee for attending the meeting. Mrs McKee left the meeting before the Group's discussion and decision-making.

It was confirmed that:

- SMC 1109/15 takes account of the benefits of a PAS that improves the cost-effectiveness of Akynzeo® ▼
- the submitting company requested that SMC only considered Akynzeo® ▼ when positioned for use in the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy. Akynzeo® ▼ is also licensed for the prevention of acute and delayed nausea and vomiting associated with moderately emetogenic cancer chemotherapy.
- there is no data comparing the different NK1 and 5-HT3 receptor antagonists used in combination, therapeutic equivalence is unknown
- there is no data available for the use of Akynzeo® ▼ in patients receiving multiple-day chemotherapy regimens
- netupitant is not available as a single agent product, it is only available in combination with palonosetron as Akynzeo® ▼
- the patent for palonosetron expired 11/2015, the patent for aprepitant is due to expire towards the end of 2018

Items 7.3, 8.1, 8.2 were taken together.

The Group accepted that antiemetic failure could have negative consequences for patients, and management of antiemetic failure entails an additional service impact for the managed service and Primary Care. Effective prevention of acute and delayed chemotherapy-

induced nausea and vomiting will provide significant benefits for patients and NHS Grampian.

8.1. FG1 SMC 1109/15 – AKYNZEO® (HIGHLY EMETOGENIC CISPLATIN-BASED CHEMOTHERAPY)

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

The Group accepted the restricted local need for Akynzeo® ▼ as outlined in SMC 1109/15.

SMC 1109/15 - Netupitant/palonosetron 300mg/0.5mg hard capsule (Akynzeo®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: in adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy.
In patients receiving a first course of highly emetogenic cisplatin-based chemotherapy, treatment with netupitant/palonosetron plus dexamethasone resulted in a significantly higher proportion of patients achieving no emesis and no breakthrough medication compared with palonosetron plus dexamethasone.
This advice takes account of the benefits of Patient Access Scheme (PAS) that improves the cost-effectiveness of netupitant/palonosetron 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. **FTeam**

8.2. FG1 393/16 AKYNZEO® ▼ (ANTIEMETIC FAILURE)

The Group accepted the restricted local need for Akynzeo® ▼ as an option for the prevention of acute and delayed nausea and vomiting associated with moderately or highly emetogenic cancer chemotherapy in adult patients who have experienced antiemetic failure, i.e. not first-line choice, but allowing step-up in antiemetic choice prior to the next chemotherapy cycle.

Netupitant/palonosetron 300mg/0.5mg hard capsule (Akynzeo®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for the prevention of acute and delayed nausea and vomiting associated with moderately or highly emetogenic cancer chemotherapy in adult patients who have experienced antiemetic failure.
Restriction: nausea and vomiting of Grade 2 and above despite use of breakthrough antiemetics. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. **FTeam**

7.3. FORMULARY REVIEW - ANTIEMETIC FORMULARY REVIEW

A member declared a non-personal, non-specific interest in Merck Sharp & Dohme Limited, and participated in the discussion and decision-making.

The Group considered the SBAR submitted as part of an overarching review of antiemetics that will be used in conjunction with the development/update of NOSCAN antiemetic guidelines.

The Group supported the recommendations presented by the service.

Aprepitant 80mg, 125mg hard capsules (Emend®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: in patients who have experienced antiemetic failure according to NOSCAN guidelines. Aprepitant is given as part of a combination therapy.
Restriction: nausea and vomiting of Grade 2 and above despite use of breakthrough antiemetics. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. **FTeam**

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	SMC 678/11 - Fosaprepitant dimeglumine (IVEmend 150mg®) is included on the Grampian Joint Formulary for the indication in question; restricted use. Indication under review: prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy in adults. IVEmend 150mg is given as part of a combination therapy. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only.	**FTeam**
	Fosaprepitant dimeglumine (IVEmend 150mg®) is included on the Grampian Joint Formulary for the indication in question; restricted use. Indication under review: in patients who have experienced antiemetic failure according to NOSCAN guidelines. IVEmend 150mg is given as part of a combination therapy. Restriction: nausea and vomiting of Grade 2 and above despite use of breakthrough antiemetics. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only.	**FTeam**
	SMC 895/13 - Granisetron 3.1mg/24 hours transdermal patch (Sancuso®) is included on the Grampian Joint Formulary for the indication in question; restricted use. Indication under review: in adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral antiemetic administration is complicated by factors making swallowing difficult. Granisetron 3.1mg / 24 hours transdermal patch is slightly more expensive than the oral formulation. It provides an alternative option in patients who have difficulty swallowing oral medication. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only.	**FTeam**
	SMC 912/13 - Ondansetron 4mg, 8mg orodispersible films (Setofilm®) is not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question. Indication under review: In adults: • Prophylaxis of acute nausea and vomiting induced by moderately emetogenic chemotherapy. • Prophylaxis and treatment of delayed nausea and vomiting induced by moderately to highly emetogenic chemotherapy. • Prophylaxis and treatment of acute and delayed nausea and vomiting induced by highly emetogenic radiotherapy. • Prophylaxis and treatment of post-operative nausea and vomiting (PONV). In paediatric populations: • Management of chemotherapy-induced nausea and vomiting in children aged ≥6 months. • Prophylaxis and treatment of post-operative nausea and vomiting (PONV) in children aged ≥4 years. Restriction: ondansetron orodispersible films are restricted to use in patients with an enhanced risk of aspiration or who experience difficulties in swallowing. Generic preparations of ondansetron are available at a lower cost than the proprietary products. Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question.	**FTeam**
	SMC 838/13 - Palonosetron 500microgram soft capsules (Aloxi®) is not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question. Indication under review: prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults. At recommended licensed doses the soft capsule formulation has been shown to be clinically non-inferior to the intravenous formulation and is cost neutral. SMC has previously accepted palonosetron intravenous injection for the prevention of nausea and vomiting associated with moderately emetogenic cancer	

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chemotherapy.
Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question. **FTeam**

SMC 208/05 - Palonosetron 250micrograms solution for injection (Aloxi®) is not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question
Indication under review: for the prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.
Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question. **FTeam**

4. MATTERS ARISING

4.1. FG1 SMC 1096/15 - LENALIDOMIDE (MULTIPLE MYELOMA)

A member declared a personal, non-specific interest in relation to this product, and participated in the discussion and decision-making.

At the May meeting, the Group was minded to include lenalidomide on the formulary as per SMC 1096/15, but requested clarification of the criteria used to identify patients who are unsuitable for thalidomide-containing regimens.

The Group noted:
- SMC was asked to consider lenalidomide when positioned for use in patients who are unsuitable for thalidomide containing regimens
- lenalidomide:
  - has been designated an orphan medicinal product for multiple myeloma and meets SMC orphan criteria
  - was accepted for use in NHS Scotland following the output from the PACE process, and after application of the appropriate modifiers
  - is a thalidomide derivative, but has a different toxicity profile to thalidomide

The Group acknowledged the criteria submitted by the service, noting that multiple myeloma is an incurable, relapsing and remitting cancer, that treatment is complex, and patients will receive all treatment options at some point in their care.

The Group accepted the restricted local need for lenalidomide (plus low-dose dexamethasone) for the treatment of adult patients unsuitable for thalidomide-containing regimens with previously untreated multiple myeloma who are not eligible for transplant.

SMC 1096/15 - Lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg, 25mg capsules (Revlimid®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.
Restriction: for use in patients unsuitable for thalidomide-containing regimens.
Continuous lenalidomide plus low-dose dexamethasone, compared with melphalan, prednisolone plus thalidomide, significantly improved progression-free survival in treatment-naive patients with newly diagnosed multiple myeloma who were not eligible for transplant. Overall survival data are immature, but interim analyses suggest a survival benefit for lenalidomide plus low-dose dexamethasone compared with melphalan, prednisolone plus thalidomide.
This submission focuses on lenalidomide in combination with dexamethasone. Lenalidomide is also licensed for use in combination with melphalan and prednisolone for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant. The submitting company did not provide evidence for SMC assessment therefore SMC cannot recommend this combination for use in this treatment setting.
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

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	supervised by a physician experienced in the use of anticancer therapies.	**FTeam**

4.2. Replacement for Grampian Medicines Management website

Ms Doney will send details of the replacement for the current formulary website.

7. OTHER BUSINESS

7.1. NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE) (MULTIPLE) TECHNOLOGY APPRAISAL (MTA) GUIDANCE

The Group noted the recommendations of NICE TA390 – Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes. This NICE MTA guidance supersedes the SMC advice for monotherapy only and Healthcare Improvement Scotland advises that the recommendations are as valid for Scotland as for England and Wales.

Dr Counter provided the Group with a comprehensive review of the EMPA-REG OUTCOME trial. The aim of the trial was to compare the effect of empagliflozin versus placebo on cardiovascular morbidity and mortality in patients with type 2 diabetes at high risk for cardiovascular events who were receiving standard care.
The primary composite outcome was death from cardiovascular causes, non-fatal myocardial infarction, or non-fatal stroke, as analysed in the pooled empagliflozin group versus the placebo group. The key secondary composite outcome was the primary outcome plus hospitalisation for unstable angina.

The main findings:

- amongst a population of type II diabetics at high risk of cardiovascular events:
  - empagliflozin was associated with a lower incidence of composite outcome cardiovascular death and non fatal MI or stroke
  - the predominant driver is reduction in cardiovascular death
  - all-cause mortality reduced in those receiving empagliflozin over the study period
  - amongst the non-fatal cardiovascular outcomes, only incidence of hospitalisation for heart failure was significantly different between the placebo and empagliflozin groups
  - neither individual empagliflozin dose arm showed a significant difference in any cardiovascular outcome compared with placebo
  - no significant difference in cardiovascular outcomes were seen between the two dose arms of empagliflozin
  - small dose related effects on HBA1c, weight, HDL cholesterol
  - other than genital infection, empaglifozin was not associated with increased adverse events

The Group discussed the findings of the EMPA-REG OUTCOME trial noting that it is the first anti-diabetic drug, after metformin, that reduces cardiovascular mortality.

It was confirmed that the diabetic service is currently reviewing the anti-diabetic medicines included on the formulary. In view of the EMPA-REG OUTCOME trial and because the European Medicines Agency is currently reviewing canagliflozin the Group was of the opinion that empagliflozin should be considered the preferred formulary choice sodium-glucose co-transporter 2 inhibitor. The diabetic service lead will be invited to the next meeting to discuss the choice of anti-diabetic medicines. **FD**

The Group accepted the restricted local need for empagliflozin as licensed for the treatment of type 2 diabetes mellitus.

Empagliflozin 10mg, 25mg tablets (Jardiance®) is included on the Grampian Joint Formulary for the indication in question; pending protocol.
Indication under review: for the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as:

- **monotherapy when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance.**
- **add-on combination therapy, in combination with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise,**

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do not provide adequate glycaemic control.
It was classified 1b - available for restricted use under specialist supervision and 8d – treatment may be initiated in the community on the recommendation of a consultant/specialist. [Specialist to include GP/non-medical prescriber with a specialist interest in diabetes]. **FTeam**

7.2. CONFLICTS OF INTEREST

Members were reminded that Disclosure UK will go live on the ABPI website by July. Disclosure UK is a searchable database that shows payments and benefits in kind made by the pharmaceutical industry to doctors, nurses and other health professionals and organisations in the UK.

8. NEW PRODUCT REQUESTS

8.3. FG1 SMC 1086/15 - PEMBROLIZUMAB (ADVANCED MELANOMA)

A member declared a non-personal, non-specific interest in Merck Sharp & Dohme Limited, and participated in the discussion and decision-making.

The Group considered the submission for pembrolizumab as monotherapy for the treatment of advanced melanoma in adults previously untreated with ipilimumab.

The Group noted:
- pembrolizumab:
  - meets SMC end of life and orphan equivalent criteria
  - was accepted for use in NHS Scotland following the output from the PACE process, and after application of the appropriate modifiers
  - offers an alternative medicine to ipilimumab, with an improved progression-free survival and overall survival
- the submitting company requested that SMC considers the use of pembrolizumab for patients with unresectable or metastatic melanoma untreated with ipilimumab
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of pembrolizumab
- pembrolizumab and ipilimumab are given by intravenous infusion every three weeks, but pembrolizumab is given until disease progression unlike ipilimumab that is given for a maximum of four cycles

The Group considered that the introduction of pembrolizumab could have significant financial implications and service implications. The Group accepted the restricted local need for pembrolizumab as outlined in SMC 1086/15.

SMC 1086/15 - Pembrolizumab 50mg powder for concentrate for solution for infusion (Keytruda®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: as monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously untreated with ipilimumab.
In a phase III randomised open-label study, treatment with pembrolizumab (at unlicensed doses) extended median progression free survival and overall survival compared with other immune therapy in patients with advanced melanoma previously untreated with ipilimumab.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pembrolizumab 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 specialist physicians experienced in the treatment of cancer. **FTeam**

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8.4. FG1 390/15 - LYMPHOCYTE IMMUNE GLOBULIN, ANTI-THYMOCYTE GLOBULIN [EQUINE] STERILE SOLUTION (ATGAM®) [UNLICENSED PRODUCT] (APLASTIC ANAEMIA)

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

The Group considered the submission for the unlicensed product equine anti-thymocyte globulin (ATG).

The Group noted:

- aplastic anaemia treatment guidelines for adults and children recommend the use of horse ATG
- immunosuppressive therapy with ATG (usually with ciclosporin) has been the standard first-line treatment for patients with aplastic anaemia who are not eligible for hematopoietic stem cell transplantation (HSCT) for decades. It is considered a first-line option where allogeneic stem cell transplant is not deemed the best first-line therapy. Therapy may be repeated after at least 6 months in the case of relapse or partial response if allogeneic stem cell transplant is not an option.
- allogeneic stem cell transplant remains an option for relapsed/refractory patients and should be considered first-line in all patients under the age of 40 with severe aplastic anaemia where there is a suitable donor
- there are currently no licensed products available, aletuzumab, was withdrawn from the market circa 2012
- rabbit ATG (Thymoglobuline®) has shown inferior outcomes compared to horse ATG
- there is no direct cost-effectiveness data, however the overall treatment cost is not prohibitive, and there are not any other medicines coming to market for this indication in the near future
- no additional service impact is anticipated because of the small patient numbers and treatment has been available via individual treatment requests
- anaphylaxis is uncommon but a serious side-effect that may occur at any time during therapy with ATGAM®. Use will be restricted to prescribing only by Consultant Haematologists, in line with national prescribing guidance.

The Group accepted the restricted local need for the unlicensed product anti-thymocyte globulin [equine] (ATGAM®) as a treatment option for aplastic anaemia in a small group of patients.

Lymphocyte immune globulin, anti-thymocyte globulin [equine] sterile solution (ATGAM®) [unlicensed product] is available for the indication in question; restricted use.
Indication under review: aplastic anaemia in adults and children.
Restriction: prescribing is limited to Consultant Haematologists in line with national guidance.
It was classified 3a – unlicensed product and 8b – recommended for hospital use only. Informed consent should be obtained and documented. Only physicians experienced in immunosuppressive therapy in the treatment of aplastic anemia patients should use ATGAM®. Treatment must be given as an in-patient, and should only be administered in centres that are familiar with its use. **FTeam**

8.5. SMC 1043/15 BUDESONIDE (BUDENOFALK®) – (AUTOIMMUNE HEPATITIS)

The Hepatology Team confirmed that a local submission for SMC 1043/15, budesonide 3mg gastro-resistant capsules (Budenofalk®) for the treatment of autoimmune hepatitis, will not be progressed.

SMC 1043/15 - Budesonide 3mg gastro-resistant capsules (Budenofalk®) is not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question.
Indication under review: autoimmune hepatitis.
Restriction: for use in non-cirrhotic patients who are intolerant of conventional oral corticosteroids (prednisolone) with severe corticosteroid-related side effects (actual or anticipated) such as psychosis, poorly controlled diabetes or osteoporosis.
In a phase IIb study, a significantly greater proportion of patients with non-cirrhotic

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autoimmune hepatitis achieved complete biochemical remission and a reduction in predefined corticosteroid-specific side effects when treated with budesonide plus an immunosuppressant compared with an alternative corticosteroid plus an immunosuppressant.
Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED JUNE 2016

The Group noted the SMC provisional advice issued June 2016.

The Chairman highlighted that the holder of the marketing authorisation for adalimumab did not make a submission to SMC for the licence extension for the treatment of chronic plaque psoriasis, SMC 1173/16. It was confirmed that this negative advice will not affect current practice and SMC 468/08 remains the extant advice.

If published next month the non-submission statements, for adalimumab (Humira®) SMC 1173/16, afatinib (Giotrif®) ▼ SMC 1174/16, azacitidine (Vidaza®) SMC 1175/16 and ramucirumab (Cyramza®) ▼ SMC 1176/16, will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED JUNE 2016

The Group noted the SMC advice published June 2016.

Following publication of the negative SMC recommendations for cabazitaxel (Jevtana®) SMC 735/11 and evolocumab (Repatha®) ▼ SMC 1148/16, and the non-submission statements for eltrombopag olamine (Revolade®) SMC 1164/16, ramucirumab (Cyramza®) ▼ SMC 1165/16 and ruxolitinib phosphate (Jakavi®) ▼ SMC 1166/16, these will not be included on the Grampian Joint Formulary for the indications in question.

The following SMC accepted medicines have not been processed within a 60-day timescale:

- SMC 316/06 co-careldopa (Duodopa®) intestinal gel (submission received)
- SMC 1145/16 blinatumomab (Blincyto®) ▼ (submission expected)
- SMC 1149/16 mepolizumab (Nucala®) ▼ (submission expected)
- SMC 1153/16 febuxostat (Adenuric®) (submission expected)

Local advice for these medicines and indications will be included in the June 2016 decisions as 'Not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question.' **FTeam**

SMC 1154/16 - NAPROXEN 250MG EFFERVESCENT TABLETS (STIRLESCENT®)

The Group reviewed the abbreviated SMC advice, SMC 1154/16, for naproxen 250mg effervescent tablets and the document tabled at the meeting that showed the relative costs of different formulations of naproxen.

It was confirmed that:

- naproxen liquid was previously only available as an unlicensed product (250mg/5mL) but recently a licensed product has become available, naproxen 25mg/mL oral suspension manufactured by Orion Pharma
- diclofenac dispersible tablets (Voltarol®) have been discontinued by the manufacturer
- there is currently no experience of administration of Stirlescent® via enteral tubes

The Group noted the significant cost difference between different naproxen formulations and that naproxen as 250mg effervescent tablets costs considerably less than equivalent doses of naproxen 25mg/mL oral suspension.

The Group did not support formulary inclusion for naproxen 25mg/mL oral solution or naproxen 250mg effervescent tablets, and requested the non-formulary status is highlighted on ScriptSwitch. **FD/AD**

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	SMC 1154/16 - Naproxen 250mg effervescent tablets (Stirlescent®) is not included on the Grampian Joint Formulary because the NHS board decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already in the formulary. Indication under review: treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute musculoskeletal disorders, dysmenorrhoea and acute gout in adults. Restriction: use in patients unable to swallow naproxen tablets. Naproxen 250mg effervescent tablets (Stirlescent®) have demonstrated bioequivalence to naproxen 250mg tablets. The effervescent tablet formulation provides an alternative for patients who cannot swallow tablets. They are more expensive than generic naproxen tablets but cost less than unlicensed naproxen oral liquid (special formulation). Another non-steroidal anti-inflammatory drug is available in dispersible form and may cost less than naproxen when the higher dose of naproxen is required. It was classified 2a - approved by the SMC but currently not recommended for use in NHS Grampian. Cost effective alternatives are available.	**FTeam**
	Naproxen Orion 25mg/mL oral suspension is not included on the Grampian Joint Formulary because the NHS board decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary. Indication under review: for the treatment of: • **rheumatoid arthritis, spondyloarthropathies (including ankylosing spondylitis), osteoarthrosis, acute gout, acute musculoskeletal disorders with pain, dysmenorrhoea in adults.** • **juvenile rheumatoid arthritis in children aged over 5 years** **It was classified 2c - not recommended for use in NHS Grampian. Cost effective alternatives are available.**	**FTeam**
11.	GENERAL INFORMATION FROM SMC JUNE 2016 - NONE	
13.	AOCB - NONE	

DATE OF NEXT MEETING

Tuesday 19 July 2016 starting at 14:30 in the Aspen Room Forest Grove House.

CHAIRMAN'S SIGNATURE  **DATE 19 July 2016**