NHS GRAMPIAN
Minute of Formulary Group Meeting held on Tuesday 19th May 2015
in the Aspen Room, Forest Grove House

PRESENT	APOLOGIES	APPROVED
Dr D Counter	Dr D Culligan	
Ms A Davie	Dr A MacDonald	
Ms F Doney	Mr M Paterson	
Mr A Duncan (until item 7.6)		
Mrs L Harper (from item 3.7)		
Dr C Hind		
Professor J McLay (Chairman)		
Mrs L Montgomery		
Dr W Moore		
Mr C Rore		
Mr R Sivewright		

IN ATTENDANCE
Ms Kate Robertson, Secretary, Formulary Team.
Dr Jane Tighe, Consultant Haematologist and Unit Clinical Director, Anchor Unit, to discuss the haematology submissions.

OBSERVER
Ms Elaine Sheridan, Medicines Information Pharmacist.

ITEM **SUBJECT** **ACTION**

Note some items were taken out of agenda order.

1. APOLOGIES

The Chairman welcomed members to the meeting and apologies for absence were requested and noted.

2. DRAFT MINUTE OF THE MEETING HELD ON THE 21ST APRIL 2015

The Group accepted the draft note of the meeting held on the 21st April 2015 as an accurate record of the meeting subject to minor typographical changes. **FD**
The approved final minute will be in the public domain within 21 days. **FTeam**

3. MATTERS ARISING

3.1. GP REPRESENTATION ON THE FORMULARY GROUP

Mr Pfleger, Chairman of the Grampian Medicines Management Group (GMMG), has confirmed that letters have been sent to the Integrated Joint Board Leads and associated GP Leads requesting nominations for the GP vacancies on the three medicines management groups (GMMG, Formulary Group and Medicines Guideline and Policies Group (MGPG)). A further update will be provided when available. **FD**

Items 3.2 and 3.3 were deferred and discussed with the new product requests.

3.4. FG1 SMC 1009/14 TRIUMEQ® ▼ - HUMAN IMMUNODEFICIENCY VIRUS

Clarification of the cost and offset related to the introduction of Triumeq® ▼ was carried over from the January meeting. The Group noted the document submitted by the Specialist Antibiotic Pharmacists confirming the costs of Triumeq® ▼, a new combination tablet containing the three antiviral agents dolutegravir (50mg), abacavir (600mg) plus lamivudine (300mg), versus other first-line treatment options. Colleagues in finance to note that an additional budget allocation is not required to allow the introduction of Triumeq® ▼. **RS**

3.5. NHSSCOTLAND BIOSIMILARS FRAMEWORK (UPDATE)

The Group noted NHS Grampian's response to the draft NHSScotland biosimilars framework.
At the March meeting it was not known if batch numbers were recorded at the time of administration of biologics. It was confirmed that batch numbers are recorded, and that current systems will be amended to allow the introduction of biosimilar medicines to ensure

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that the medicine, brand name and batch number are recorded at the time of administration.

3.6. FOSFOMYCIN IV INFUSION

The Group noted advice from the Specialist Antibiotic Pharmacists that an intravenous (IV) to oral switch would be considered for fosfomycin IV infusion where possible and would be guided by microbiology sensitivities.

3.7. INSULIN DEGLUDEC (TRESIBA® ▼)

The Group noted that in the absence of a submission insulin degludec is not recommended for use in NHSScotland, SMC 1060/15. Insulin degludec has a long half-life (~25 hours). Following a clinical trial, the paediatric service has experience in the use of insulin degludec, and is using it for a very small number of non-compliant, very poorly controlled diabetic paediatric patients who were ketotic every day. The long half-life provides a degree of control that is not possible with the other recommended long-acting insulins. As paediatric patients may become ketotic and acidotic very quickly, the Group agreed with the service that insulin degludec was essential for a small group of patients and a Group Treatment Request should be progressed. Ms Doney to send the relevant paperwork to Dr Sun. **FD**

HAEMATOLOGY SUBMISSIONS

Dr Jane Tighe, Unit Clinical Director, Anchor Unit, attended the meeting to discuss the haematology submissions and left the meeting before decision-making.

BOSUTINIB AND PONATINIB

Dr Tighe described the current treatment options for chronic myelogenous leukaemia (CML) and where the new third generation tyrosine kinase inhibitors (TKIs), bosutinib and ponatinib, would be used. Noting that most use will be in chronic phase CML patients. There is little data regarding the order/sequencing of TKIs. CML treatment guidelines are still evolving. Trials are investigating outcomes based on patients' initial response with continued and/or interrupted TKI treatment. The introduction of generic imatinib has the potential to change practice (nilotinib current first-line TKI, ref TA 251). Ponatinib is the only TKI that is effective in the presence of the T315I kinase domain mutation.

RUXOLITINIB

Dr Tighe described the symptoms of myelofibrosis and that ruxolitinib improves constitutional symptoms. The company has new data that is suggesting a survival benefit [unpublished and not presented in SMC Detailed Advice Document (DAD)]. The department has experience in the use of ruxolitinib, having accessed it on an individual patient basis. Response is quick, with symptoms returning within a week of stopping ruxolitinib. Treatment will be discontinued if no symptomatic improvement, however there may be a cohort of patients where ruxolitinib is very difficult to discontinue.

IDELALISIB (CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL) AND FOLLICULAR LYMPHOMA (FL))

Dr Tighe described the treatment options for CLL, including the use of unlicensed alemtuzumab. CLL is an indolent condition where watch and wait is appropriate for some patients with others requiring treatment. Idelalisib is a first in class agent used in combination with rituximab 1) for treatment-naïve patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy and 2) for patients with relapsed CLL who are unsuitable for chemotherapy.

Dr Tighe described the treatment options for FL and that idelalisib would be a third-line option for patients. There was considerable debate about the understanding of relapsed and refractory within haematology versus the meaning within the SMC DAD for FL.

4. FORMULARY GROUP DECISIONS APRIL 2015 – PUBLISHED 01/05/2015

The Group ratified the advice as published. **FTeam**

5. CMO(2012)1 REPORTING FOR SCOTTISH MEDICINES CONSORTIUM (SMC) ADVICE – 2015/16 YTD

It was confirmed that for the SMC accepted medicines published April 2015, the Formulary

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Group audit standard for CMO(2012)1 reporting was achieved for the following criteria:
- Local decision on SMC accepted medicine published within 90 days: 8 of 8 - 100%
- FG decision published within 14 days of the decision being reached: 8 of 8 - 100%

6. OTHER BUSINESS

6.1. NICE MULTIPLE TECHNOLOGY APPRAISALS - NONE

6.2. PROPOSED APPROACH TO DEVELOPING NATIONAL RECOMMENDATIONS FOR ADTC RATIFICATION ON THE PLACE OF HEPATITIS C MEDICINES IN TREATMENT PROTOCOLS

The Group noted the paper outlining the proposed approach to developing national recommendations for Hepatitis C medicines.

6.3. COMPLETE THE CYCLE (UPDATE)

This item was deferred to a future meeting.

7. NEW PRODUCT REQUESTS

7.1. FG1 SMC 921/13 – DYMISTA® NASAL SPRAY- SEASONAL AND PERENNIAL ALLERGIC RHINITIS

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

The Group considered the submission for Dymista® for the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis as per SMC 921/13.

The Group noted:
- Dymista®:
  - contains azelastine and fluticasone in a nasal spray
  - is the only combination intranasal antihistamine and corticosteroid preparation
  - is taken twice daily
- the treatment pathway proposed by the requestor, as a last line choice for Primary Care before referral to specialists
- that use is subject to a Patient Access Scheme (PAS) or a list price that is equivalent or lower

The Group accepted the local need for Dymista® as a last line option for Primary Care clinicians before referral to specialists when current standard therapy choices fail or are not tolerated and allergic rhinitis remains uncontrolled and difficult for the patient.

SMC 921/13 - Azelastine hydrochloride 137micrograms plus fluticasone propionate 50micrograms per actuation nasal spray (Dymista®) is included on the Grampian Joint Formulary for the indication in question.
Indication under review: adults and adolescents (12 years and older) for the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.
Restriction: use is limited to patients where current standard therapy choices (i.e. intranasal antihistamine or glucocorticoid) are not effective or not tolerated and allergic rhinitis remains uncontrolled and difficult for the patient.
For patients in whom the combination of azelastine hydrochloride and fluticasone propionate nasal spray is an appropriate choice of therapy, Dymista® provides the two ingredients in a single nasal spray.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Dymista® 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 1a – available for general use and 8e - treatment may be initiated in either hospital or community. **FTeam**

7.2. FG1 381/15 – ANIDULAFUNGIN – INVASIVE CANDIDIASIS IN NEUTROPENIC ADULTS

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

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The Group considered the formulary submission from the Antimicrobial Management Team (AMT) for the licence extension of anidulafungin.

The Group noted:
- anidulafungin is already included on the formulary as per SMC 465/08 - for the treatment of invasive candidiasis in adult non-neutropenic patients, restricted to patients who are unable to tolerate fluconazole or have invasive candidiasis that is resistant to fluconazole
- the licence for anidulafungin was extended to include use in neutropenic adult patients
- the licence extension is considered out of remit for SMC
- caspofungin is the first-line echinocandin used in haematology due to its licence in neutropenic patients and evidence base, and anidulafungin would be an alternative to caspofungin
- that the AMT supports the formulary inclusion of anidulafungin to allow use in neutropenic adult patients

The Group accepted the restricted local need for anidulafungin as presented by the AMT, subject to update of the 'alert antimicrobial guidance. **AbPh**

Anidulafungin 100mg powder for concentrate for solution for infusion (ECALTA®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: invasive candidiasis in neutropenic adults.
Restriction: for the treatment of invasive candidiasis in patients unable to tolerate fluconazole or with invasive candidiasis resistant to fluconazole. Anidulafungin is a restricted antifungal for use only on the advice of a Medical Microbiologist, Infection specialist or Haematologist and inclusion in the NHS Grampian Staff Guidance For Optimising Use Of Alert (Restricted) Antimicrobials In Adults. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment with anidulafungin should be initiated by a physician experienced in the management of invasive fungal infections. **FTeam**

7.3. FG1 SMC 1026/15 – IDELALISIB – CHRONIC LYMPHOCYTIC LEUKAEMIA

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

The Group considered the submission for idelalisib for chronic lymphocytic leukaemia (CLL).

The Group noted:
- idelalisib:
  - for CLL, was accepted for use within NHS Scotland in the context of SMC decision modifiers
  - is a first-in-class agent, that is taken orally twice a day
  - treatment should be continued until disease progression or unacceptable toxicity
- the discrepancy between the local estimate of patients eligible for treatment and that submitted by the manufacturer to SMC, and the manufacturers estimated uptake
- the flat-pricing for 100mg and 150mg tablets and that use is subject to a PAS

The Group accepted the restricted local need for idelalisib as per SMC 1026/15 for patients with relapsed CLL who are unsuitable for chemotherapy and treatment naïve patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy.
To allow the introduction of idelalisib for the treatment of CLL as per SMC 1026/15 an estimate of £136,000 was agreed and will be highlighted with finance. **RS**

SMC 1026/15 - Idelalisib 100mg and 150mg tablets (Zydelig®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL):
- **who have received at least one prior therapy, or**
- **as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.**

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Restriction: patients with relapsed CLL who are unsuitable for chemotherapy and treatment naïve patients with 17p deletion or TP53 mutation who are unsuitable for chemo-immunotherapy.
Idelalisib in combination with an anti-CD20 antibody significantly improves progression free survival compared with an anti-CD20 antibody alone in patients with relapsed CLL. The treatment effect across subgroups with 17p deletion and/or TP53 mutation was consistent with that of the total study population.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of idelalisib 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 with idelalisib should be conducted by a physician experienced in the use of anticancer therapies. **FTeam**

7.4. FG1 SMC 1039/15 – IDELALISIB – FOLLICULAR LYMPHOMA

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

The Group noted that:

- idelalisib:
  - for follicular lymphoma (FL) refractory to two prior lines of treatment, meets SMC ultra-orphan and end of life criteria
  - is a first-in-class agent, that is taken orally twice a day
  - treatment should be continued until disease progression or unacceptable toxicity
- the flat-pricing for 100mg and 150mg tablets and that use is subject to a PAS
- the discrepancy between the local estimate of patients eligible for treatment and that submitted by the manufacturer to SMC
- treatment of adult patients with follicular lymphoma that is refractory to two prior lines of treatment depends on a number of patient factors including performance status, duration of disease, histology and duration of response to prior treatment

The Group debated at the length the terms refractory and relapsed. Dr Culligan will be invited to a future meeting to engage in a further discussion about terminology and disease pathology. **FD**

The Group expressed concern about companies requesting review of a 'niche' of the licensed indication and the presentation of the estimated patient numbers and budget impact included in SMC DADs. The Group felt that whilst provided by the submitting company it may appear that the information is SMC generated and validated. The Chairman will write to the SMC to express the Group's concerns. **JMcL/FD**

The Group accepted the restricted local need for idelalisib as monotherapy for the treatment of adult patients with FL that is refractory to two prior lines of treatment.
To allow the introduction of idelalisib for the treatment of FL as per SMC 1039/15 an estimate of £75,000 was agreed and will be highlighted with finance. **RS**
Use is subject to audit and presentation of the data at a future meeting (6 – 12 months). **FTeam**

SMC 1039/15 - Idelalisib 100mg and 150mg tablets (Zydelig®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment.
Idelalisib demonstrated clinical activity, measured by overall response rate, in a phase II non-comparative study.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of idelalisib 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 with idelalisib should be conducted by a physician experienced in the use of anticancer therapies. **FTeam**

Items 7.5 and 3.3 were taken together

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7.5. FG1 SMC 1032/15 – PONATINIB – CHRONIC MYELOID LEUKAEMIA AND PH+ ALL

3.3. FG1 SMC 910/13 BOSUTINIB – PH+ CHRONIC MYELOGENOUS LEUKAEMIA

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

The Group noted:

- that tyrosine kinase inhibitors (TKIs) have transformed the treatment of chronic myeloid leukaemia (CML)
- if left untreated or if TKIs fail, patients with CML will progress through symptoms that gradually increase in severity
- the duration of untreated chronic phase CML is three to five years
- bosutinib and ponatinib are third generation TKIs, taken orally once a day, and will be treatment options for the same patient group
- that dasatinib is not recommended for use in NHSScotland for the treatment of chronic phase, accelerated phase, or blast phase CML, ref NICE TA241 and TA251

SMC 1032/15 - PONATINIB

The Group considered the submission for ponatinib as per SMC 1032/15 for the two indications CML and Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL).

The Group noted that:

- ponatinib:
  - meets SMC orphan criteria for CML and meets both orphan and end of life criteria for Ph+ ALL
  - was accepted for use within NHS Scotland in the context of SMC decision modifiers and the output of the PACE process
  - provides a treatment option for Ph+ ALL patients and would be first-line for those with a T315I kinase domain mutation
  - requires additional monitoring; cardiovascular status of the patient should be assessed, including history and physical examination, and cardiovascular risk factors should be actively managed
  - unlike other TKIs, ponatinib is associated with pancreatitis
- the high cost of treatment (£5,656 per 28-day/£73,528 pa, inc VAT), and use is not subject to a PAS
- dose de-escalation to 30mg daily is cost-neutral not cost-saving

The Group accepted the local need for ponatinib as directed in SMC 1032/15.

SMC 1032/15 - Ponatinib 15mg and 45mg film-coated tablets (Iclusig®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use. Indication under review: adult patients with:

- **chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation**
- **Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.**

A non-comparative phase II study of ponatinib was conducted with primary outcomes of major cytogenetic response in patients with baseline chronic phase CML and major haematologic response in patients with baseline accelerated or blast phase CML or Ph+ ALL. Ponatinib demonstrated efficacy in heavily pre-treated CML and Ph+ ALL patients who had received dasatinib/nilotinib as second-line or further line tyrosine kinase inhibitor therapy or who had the T315I mutation. 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. Therapy should be initiated by a physician experienced in the diagnosis and treatment of patients with leukaemia. **FTeam**

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Due to very low Ph+ ALL patient numbers in NHSScotland the costs for this indication were not considered. If eligible patients are identified this would represent a risk to the haematology budget. **RS**

SMC 910/13 - BOSUTINIB

The Group considered the submission for bosutinib for the treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.

The Group noted:

- bosutinib
  - is licensed for patients previously treated with one or more tyrosine kinase inhibitors **and** for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options
  - was designated an orphan medicinal product for the treatment of CML by the European Medicines Agency (EMA)
  - meets SMC ultra-orphan criteria and was accepted for use within NHS Scotland in the context of SMC decision modifiers and the output of the PACE process
- the EMA considered that only a last-line indication for patients with CML with "unmet medical need" could be considered as efficacy in first-line use was not robust and there are no relevant comparative data required for approval of second-line use
- that use is subject to a PAS

The Group accepted the restricted local need for bosutinib for the treatment of Ph+ CML as per SMC 910/13.

SMC 910/13 - Bosutinib 100mg and 500mg film-coated tablets (Bosulif®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.
Major cytogenetic response was achieved in 23/52 patients who represented "unmet medical need" within a non-comparative phase I/II study, in which the full population included 546 patients with CP, AP or BP imatinib pre-treated Ph+ CML.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of bosutinib 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. Therapy should be initiated by a physician experienced in the diagnosis and the treatment of patients with CML. **FTeam**

To allow the introduction of bosutinib and ponatinib for the treatment of CML an estimate of £70,000 was agreed and will be highlighted with finance. **RS**

3.2. FG1 SMC 867/13 RUXOLITINIB - MYELOFIBROSIS (SYMPTOMS AND SPLENOMEGALY)

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

The Group considered the submission for ruxolitinib for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post-polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.

The Group noted:

- ruxolitinib:
  - meets SMC orphan status and was accepted for use within NHS Scotland in the

context of SMC decision modifiers and the output of the PACE process
  - is a symptomatic treatment, reducing splenomegaly and systemic/constitutional symptoms
  - is taken orally twice a day and the dose is based on platelet count with doses titrated based on safety and efficacy
  - treatment would continued as long as the benefit-risk remains positive
- myelofibrosis is associated with dysregulated signalling of the Janus Associated Kinases (JAKs) JAK1 and JAK2. JAKs mediate the signalling of a number of cytokines and growth factors that are important for haematopoiesis and immune function.
- dose modification, discontinuation or reduction, may be required and the Summary of Product Characteristics provides treatment discontinuation recommendations for non-responders and for patients who have demonstrated some degree of clinical improvement. Although the potential difficulty of stopping treatment in clinical practice was acknowledged.
- symptoms return when treatment is stopped (return over a period of approximately one week)
- use is subject to a PAS
- the flat pricing for the 15mg and 20mg tablets and the maximum dose is 25mg twice daily [redacted]
- the service has experience in the use of ruxolitinib

The Group noted the lack of mortality benefit and the relatively high treatment cost. The Group accepted the restricted local need for rituximab as directed in SMC 867/13.

To allow the introduction of ruxolitinib as per SMC 867/13 an estimate of £200,000 was agreed and will be highlighted with finance. **RS**

SMC 867/13 - Ruxolitinib (as phosphate) 5mg, 15mg, and 20mg tablets (Jakavi®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.
In patients with myelofibrosis, a significantly greater proportion of patients achieved a spleen response (reduction in spleen volume of at least 35% from baseline) at 48 weeks when treated with ruxolitinib compared with best available therapy. Ruxolitinib was also associated with a greater proportion of patients reporting a clinically significant reduction in myelofibrosis-related symptoms when compared with placebo.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of ruxolitinib 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. Ruxolitinib treatment should only be initiated by a physician experienced in the administration of anti-cancer agents. **FTeam**

7.6. FG1 SMC 1036/15 – JAYDESS® ▼ – CONTRACEPTION

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

The Group noted that:
- Jaydess® ▼:
  - is already included on the formulary restricted to use within the specialist service and this submission requests use as per SMC 1036/15, i.e. no restriction
  - is a levonorgestrel intrauterine delivery system that has a lower levonorgestrel release-rate than Mirena®
  - is only licensed for contraception up to 3 years (versus 5 years for Mirena®)

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- provides patients/clinicians with another choice of long-acting reversible contraception
- is not first-choice for contraception in nulliparous women as clinical experience is limited
- has not been studied in under 18 years but the Clinical Effectiveness Unit would recommend UK medical eligibility criteria (UKMEC) classifications are followed and that the use of Jaydess® ▼ is not restricted in women under 18 years

• there are no additional training requirements for insertion/removal of Jaydess® ▼

The Group accepted the local need for Jaydess® ▼ as per SMC 1036/15 removing the previous restriction to use only within the specialist service. The service to review local Patient Group Directions and update as appropriate. **MGPG**

SMC 1036/15 - Levonorgestrel 13.5mg intrauterine delivery system (Jaydess®) ▼ is included on the Grampian Joint Formulary for the indication in question.
Indication under review: contraception for up to 3 years.
A phase III, open-label, randomised study confirmed the contraceptive efficacy of levonorgestrel 13.5mg 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. Healthcare professionals inserting the intrauterine delivery system should have suitable training and recertification of training such as The Faculty of Sexual and Reproductive Healthcare Letter of Competence in Intrauterine Techniques. **FTeam**

8. **SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED MAY 2015**

The Group noted the SMC provisional advice issued May 2015.

If published next month the negative SMC recommendations, based on non-submission, for cangrelor (Kengrexal® ▼) SMC 1070/15 and paclitaxel albumin (Abraxane®) SMC 1071/15 will not be included on the Grampian Joint Formulary for the indications in question.

9. **SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED MAY 2015**

The Group noted the SMC advice published May 2015.

Following publication of the negative SMC recommendations for collagenase clostridium histolyticum (Xiapex® ▼) SMC 1059/15 and insulin degludec (Tresiba® ▼) SMC 1060/15 they 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:

- budesonide (Budenofalk®) SMC 1043/15 (submission expected)
- dexamethasone intravitreal implant (Ozurdex®) SMC 1046/15 (submission received)
- entecavir (Baraclude®) SMC 1049/15
- liraglutide (Victoza®) SMC 1044/15
- ofatumumab (Arzerra® ▼) SMC 1037/15 (submission expected)
- vedolizumab (Entyvio® ▼) SMC 1045/15 (submission expected)

Local advice for these medicines and indications will be included in the May 2015 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 1050/15 - ADALIMUMAB FOR PAEDIATRIC USE (HUMIRA®)

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

The Group accepted the local need for adalimumab as per the paediatric licence extension presented in SMC 1050/15 without the need for a full submission. Use is restricted to specialists working within specialist rheumatology services including the Scottish Paediatric and Adolescent Rheumatology Network.

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SMC 1050/15 – Adalimumab 40mg solution for injection in pre-filled syringe or pen, 40mg/0.8mL solution for injection vial for paediatric use (Humira®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.
Restriction: use within specialist rheumatology services (including those working within the network for paediatric rheumatology).
Treatment of paediatric patients with adalimumab resulted in clinically relevant improvements in the number of active joints with arthritis compared with placebo at 12 weeks.
Adalimumab has previously been accepted for restricted use within NHS Scotland in combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 2 to 17 years who have had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Use is restricted to specialists working within specialist rheumatology services including the Scottish Paediatric and Adolescent Rheumatology Network (SPARN). Patients treated with adalimumab should be given the special alert card. **FTeam**

SMC 850/13 LINAGLIPTIN 5MG TABLETS (TRAJENTA®) ▼

The diabetic consultants' reviewed SMC 850/13 and confirmed that a local submission will not be progressed. The Group noted that linagliptin is not included on the formulary and supported the position presented by the diabetic team.

SMC 850/13 - Linagliptin 5mg tablet (Trajenta®) ▼ 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: the treatment of type 2 diabetes mellitus to improve glycaemic control in adults in combination with insulin with or without metformin, when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.
Linagliptin, compared with placebo, improved glycaemic control in adults with type 2 diabetes who had inadequate glycaemic control on an insulin-containing regimen.
SMC has previously accepted linagliptin for restricted use as monotherapy in combination with metformin, and in combination with a sulphonylurea and metformin. This now extends the advice to include its use in combination with insulin.
Not included on the Grampian Joint Formulary because clinicians do not support formulary inclusion for this medicine for the indication in question. **FTeam**

10. GENERAL INFORMATION FROM SMC MAY 2015 – NIL OF NOTE

11. DOCUMENTS FOR INFORMATION

Items 11.1 (Drug Safety Update April 2015), 11.2 (Controlled Drugs Accountable Officers' Network Scotland document '2015 changes to Misuse of Drugs Regulations'), 11.3 (MGPG minute 12th March 2015) and 11.4 (GMMG minute 4th March 2015) were noted.

12. AOCB - NONE

DATE OF NEXT MEETING

The date of the next meeting was confirmed as Tuesday 16th June 2015 starting at 14.30 in the Aspen Room Forest Grove House.

CHAIRMAN'S SIGNATURE **DATE 16th June 2015**