NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 18 December 2018 at 14:30 in the Seminar Room, David Anderson Building

PRESENT	APOLOGIES	APPROVED
Ms A Davie	Dr D Culligan	
Ms F Doney	Mr C Rore	
Dr L Elliot		
Dr J Fitton		
Ms M Galvin		
Mrs L Harper (from item 3)		
Dr A MacDonald		
Professor J McLay (Chairman)		
Mrs L Montgomery		
Dr W Moore (from item 3)		
Mr M Paterson		
Mr R Sivewright		

IN ATTENDANCE
Dr Saravana Kanakarajan, Consultant in Anaesthesia and Pain Medicine, Aberdeen Royal Infirmary (ARI), for items 3 and 8.1.

Note some items were taken outwith agenda order.

ITEM	SUBJECT	ACTION

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

3. PRESENTATION - CAPSAICIN 179MG (8% W/W) CUTANEOUS PATCH (QUTENZA®)

Dr Saravana Kanakarajan, Consultant in Anaesthesia and Pain Medicine, attended the meeting to discuss the request to extend the current use of capsaicin 179mg cutaneous patch in the management of peripheral neuropathic pain.

References submitted:

1. Vinik AI, Perrot S, Vinik EJ et al. Capsaicin 8% patch repeat treatment plus standard of care (SOC) versus SOC alone in painful diabetic peripheral neuropathy: a randomised 52-week, open-label, safety study. BMC Neurology 2016: 16; 251

2. Haanpaa M, Cruccu G, Nurmikko TJ et al. Capsaicin 8% patch versus oral pregabalin in patient with peripheral neuropathic pain. European Journal of Pain 2016; 20: 316-28.

3. Nooten F, Treur M, Pantiri K et al. Capsaicin 8% patch versus oral neuropathic pain medications for the treatment of painful diabetic peripheral neuropathy: A systematic literature review and network meta-analysis. Clinical therapeutics 2017; 39(4): 787-803.

Dr Kanakarajan confirmed that:

- capsaicin is a transient receptor potential vanilloid 1 receptor (TRPV1) agonist, that activates TRPV1 receptors continuously, leading to desensitisation of epidermal nerve fibres
- topical capsaicin is available as low strength creams 0.025% w/w and 0.075% w/w, the capsaicin patch provides a much higher strength topical preparation at 8% w/w
- Qutenza® is applied to the most painful skin areas (maximum of 4 patches per application), and remains in place for 30 minutes for the feet and 60 minutes for other locations. A single application may provide relief for three months or more, and treatments can be repeated every 90 days (or longer), as warranted by the persistence or return of pain.
- in 2014 Qutenza® patch was recommended by SMC for restricted use in NHS Scotland for the treatment of peripheral neuropathic pain in non-diabetic patients [previously only recommended for post-herpetic neuralgia in non-diabetic patients]
- the efficacy and safety of Qutenza® patch was established for peripheral neuropathic pain in diabetic adults (including painful diabetic neuropathy) in the STEP and PACE studies. In 2015, the licence was extended to include peripheral neuropathic pain in

diabetic patients [previously licensed for the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain]. However, use in adults with diabetes is not recommended by SMC for use in NHS Scotland due to non-submission from the Marketing Authorisation Holder.

- use will be in line with a local protocol and patients have to be assessed by a Pain Consultant before treatment is considered. Response to treatment is monitored and only continued for people that respond. If treatment is successful, patients can have up to three treatments before returning to clinic for review by a Pain Consultant.
- use is audited, and whilst only limited data is available, audit data shows that the most responsive group is post-surgical neuropathic pain (topical/peripheral nerve injury pain)
- patients can have a diagnosis of peripheral neuropathy and a co-morbid diagnosis of diabetes, i.e., peripheral neuropathy is not a consequence of the diabetes. Whereas in diabetic peripheral neuropathy, diabetes is the cause of the peripheral neuropathic pain.
- people with diabetes and peripheral neuropathic pain may benefit from treatment, however the response for diabetic peripheral neuropathic pain is poor and rarely sufficient to meet the criteria for repeat treatment (diabetic peripheral neuropathy alone is not a reason to repeat application/treatment)
- Qutenza® has potential advantages over the current oral treatment options - it is given as a single application with no need to titrate treatment. If effective, it would provide the potential for a shorter time to relief coupled with a long-lasting effect. Additionally there are no concerns about dependence/abuse potential.
- there is a move to opioid-free analgesia, and there is increasing research highlighting that exposure to opioids in the peri-operative period may predispose patients to opioid addiction at a later time
- if pain is less then there is no reason to move to opioids for pain control
- there is an increasing problem with pregabalin – addiction potential, street value and fatalities
- the Pain Service wishes to extend the use of capsaicin patch to adults with peripheral neuropathic pain, including people with diabetes

The Chairman thanked Dr Kanakarajan for attending the meeting to discuss the use of capsaicin 8% cutaneous patch and for his contribution to the discussion. Dr Kanakarajan left the meeting before decision-making.

Mrs Harper declared a non-personal, non-specific interest in Grunenthal Ltd and took part in decision-making.

The Group noted that:

- Qutenza® is included on the Grampian Joint Formulary for restricted use for non-diabetic adults either alone or in combination with other medicinal products:
  1) as per SMC 673/11 (published February 2011), for (non-diabetic) adults with post-herpetic neuralgia (PHN) who have not achieved adequate pain relief from, or who have not tolerated, conventional first- and second-line treatments
  2) for (non-diabetic) adults with peripheral neuropathic pain AND allodynia who have not achieved adequate pain relief from, or have not tolerated, conventional third- and fourth-line treatments
- Qutenza® is licensed for the requested use. [Licence: for the treatment of peripheral neuropathic pain in adults either alone or in combination with other medicinal products for pain].
- Qutenza® is restricted to use within the Pain Clinic, ARI, because:
  - the patch should be applied by a physician (or by a health care professional under the supervision of a physician), and
  - the patch requires specific precautions to be taken before handling or administering - there is a risk of occupation exposure (causing skin, eye and/or respiratory tract irritation) particularly during patch application and removal
- when submitting for the non-diabetic population the Marketing Authorisation Holder requested that the SMC considered the use of capsaicin patch only for patients who have not achieved adequate pain relief from, or had not tolerated, conventional first- and second-line treatments
- patients would have tried first- and second- line treatment options before referral to the pain clinic

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- treatment is only started following assessment by a consultant experienced in the management of peripheral neuropathic pain, and use is within the confines of a local protocol
- treatment would not be continued in non-responders
- there is cost-effectiveness data for non-diabetic patients (SMC 673/11 published October 2014); however there is no cost-effectiveness data for adults with diabetes and peripheral neuropathic pain
- if effective, capsaicin patch has the potential to provide a notable health gain for a small number of NHS Grampian patients
- the availability of an additional analgesic agent with a different side-effect profile and low addictive/abuse potential would provide a benefit to the Health Board and population of Grampian
- patient numbers are small and application of patches is limited to the Pain Clinic
- Equity: based on multidisciplinary team discussion other Health Boards use Qutenza® beyond the SMC advice
- Safety: requested for licensed use; no new safety concerns beyond those highlighted in the Summary of Product Characteristics; Educational Risk Minimisation Materials are available to reduce the risks associated with using Qutenza® [Prescribers' Administration Guide for Qutenza (capsaicin)]
- Other: provides a non-narcotic topical treatment option with a different side-effect profile to oral treatment options (avoids central adverse effects and potential for drug-drug interactions). Availability may prevent the use of oral treatment options that are subject to abuse/have dependence potential (opioids/gabapentin/pregabalin).

The Group accepted that the management of patients with peripheral neuropathic pain can be challenging and that Qutenza® provides a licensed treatment option.

Taking all of the points discussed into account the Group supported the request to expand the use of Qutenza® to include a subgroup of diabetic and non-diabetic adults with peripheral neuropathic pain. It considered that use within the confines of a local protocol was unlikely to cause harm, but had the potential to provide a health gain for a small group of NHS Grampian patients. Additionally it provides specialists in the management of neuropathic pain with another treatment option of low dependence potential.

The Group supported the restricted local need, limited to use within the Pain Clinic ARI, for capsaicin 8% patch.

Capsaicin 179mg cutaneous patch (Qutenza®) is routinely available in line with local guidance.
Indication under review: for the treatment of peripheral neuropathic pain in adults either alone or in combination with other medicinal products for pain.
Restriction: to use in patients who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments.
It was classified 1b – available for restricted use under specialist supervision [treatment should be under the supervision of a Specialist experienced in treating neuropathic pain] and 8b – recommended for hospital use only. The Qutenza® cutaneous patch should be applied by a physician or by a health care professional under the supervision of a physician. **FTeam**

1. APOLOGIES

Apologies for absence were requested and noted.

2. DRAFT MINUTE OF THE MEETING HELD 20 NOVEMBER 2018

The Group accepted the draft note of the meeting subject to correction of typographical changes, and clarification of the discussion for items 7.2 and 7.4.

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

4. MATTERS ARISING

4.1. ACTION LOG

The Chairman reported that the Action log was not available for meeting but an updated

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	version would be available for the January meeting.	FD

5. FORMULARY GROUP DECISIONS NOVEMBER 2018 - PUBLISHED 14/12/2018

5.1. FORMULARY GROUP DECISIONS NOVEMBER 2018

Ms Doney reported that the decisions of the November meeting were not published within the 14-day publication timeline. However, the percentage published within 14-days is still within audit standard (90%).

5.2. DRAFT NETFORMULARY UPDATE FOR NOVEMBER 2018 FORMULARY GROUP DECISIONS

Ms Doney confirmed the netFormulary update for the November decisions would be included in the January meeting papers.

6. NETFORMULARY/FORMULARY REVIEW

ADALIMUMAB BIOSIMILAR

The Chairman reported that adalimumab biosimilar products are available and the national contract has been awarded, and NHS Grampian's preferred adalimumab biosimilar is Amgevita® ▼.

Amgevita® ▼, marketed by Amgen, is a citrate-free product, available as 40mg and 20mg presentations. The licensed indications are the same as the originator product, Humira®, except for paediatric uveitis and paediatric hidradenitis suppurativa.

Ms Galvin declared a personal, non-specific interest in Amgen and took part in decision-making.

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

The Group supported the restricted local need for biosimilar adalimumab as a treatment option within treatment pathways for appropriate patients as identified by treating clinicians, and subject to compliance with a biosimilar medicines prescribing framework.

The Group noted Amgevita® ▼ as the preferred biosimilar adalimumab product and accepted the restricted local need for Amgevita® ▼ as licensed [eMC, date of revision of the text October 2018], without the need for a full submission.

Amgevita® ▼ (adalimumab 50mg/mL solution) is routinely available in line with local guidance.
Indications: as licensed.
Restriction: in line with SMC and Healthcare Improvement Scotland advice for the reference adalimumab product [Humira®].
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Amgevita® ▼ is indicated. Ophthalmologists are advised to consult with an appropriate specialist before initiation of treatment with Amgevita® ▼. Patients treated with Amgevita® ▼ should be given the special alert card. FTeam

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

It was reported that Benepali® ▼ remains the preferred etanercept biosimilar for NHS Grampian.

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7. OTHER BUSINESS

7.1. SMC 1337/18 - LUTETIUM (177LU) OXODOTREOTIDE (LUTATHERA®) ▼

Ms Doney reported that in July 2018 the SMC published advice for Lutathera® ▼ a lutetium^{177}-labelled somatostatin tumour-targeted peptide receptor radionuclide therapy agent. As Lutathera® ▼ requires an Administration of Radioactive Substances Advisory Committee (ARSAC) licence to administer there has been agreement that treatment will be provided from a specialist centre in Greater Glasgow and Clyde Health Board.

The Group agreed that Lutathera® ▼ will be noted as non-formulary because treatment is available from a specialist centre in another Board.

SMC 1337/18 - Lutetium (177Lu) oxodotreotide 370MBq/mL solution for infusion (Lutathera®) ▼ is available from a specialist centre in another NHS Board.
Indication under review: for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adults.
In an open-label, phase III study, lutetium (177Lu) oxodotreotide significantly improved progression-free survival compared with a high dose somatostatin analogue in patients with progressive midgut neuroendocrine tumours.
This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
Available from a specialist centre in another NHS Board.
Lutathera® ▼ should be administered only by persons authorised to handle radiopharmaceuticals in designated clinical settings and after evaluation of the patient by a qualified physician.
Before starting treatment with Lutathera® ▼, somatostatin receptor imaging (scintigraphy or positron emission tomography [PET]) must confirm the over-expression of these receptors in the tumour tissue with the tumour uptake at least as high as normal liver uptake (tumour uptake score ≥ 2). **FTeam**

7.2. ABIRATERONE AND ENZALUTAMIDE SHARE CARE PROTOCOLS (SCPS)

The Chairman reported that share care protocols are now available for the prostate cancer medicines abiraterone and enzalutamide. Prescribing will remain under the control of specialists in the hospital (prescribed on hospital-based prescription) with monitoring in Primary Care; no changes to formulary classification both remain Red [hospital only].

8. NEW PRODUCT REQUESTS

8.2. FG1SMC 1296/18 - PEMBROLIZUMAB (CLASSICAL HODGKIN LYMPHOMA)

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

The Group considered the submission for pembrolizumab for adults with relapsed or refractory classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplant and brentuximab vedotin, or who are transplant-ineligible and have failed brentuximab vedotin.

The Group noted:

- pembrolizumab:
  - is a humanised monoclonal antibody which binds to the programmed cell death-1 receptor
  - is already included on the formulary for other indications
  - is the second humanised monoclonal antibody licensed for patients with relapsed or refractory cHL
  - is administered as an intravenous infusion every three weeks at a dose of 200mg
  - [for this indication] meets SMC ultra-orphan and end of life criteria, and was accepted for use in NHS Scotland following the output from the PACE process and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of pembrolizumab

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- the local estimate of patient number is small, and that treatment could be given for up to 2 years

The Group accepted the restricted local need for pembrolizumab monotherapy for adults with relapsed or refractory cHL as outlined in SMC 1296/18.

SMC 1296/18 - Pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) ▼ is routinely available in line with national guidance (SMC 1296/18).
Indication under review: as monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant and brentuximab vedotin, or who are transplant-ineligible and have failed brentuximab vedotin.
Restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.
In a phase II study, pembrolizumab was associated with a clinically meaningful overall response rate in adults with classical Hodgkin lymphoma who had failed autologous stem cell transplant and brentuximab vedotin, or who were transplant-ineligible and had failed brentuximab vedotin.
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. Therapy must be initiated and supervised by specialist physicians experienced in the treatment of cancer. **FTeam**

8.3. FG1SMC 1219/17 - OBINUTUZUMAB (RELAPSED/REFRACTORY FOLLICULAR LYMPHOMA)

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

The Group considered the request for obinutuzumab in combination with bendamustine followed by obinutuzumab maintenance for the treatment of patients with follicular lymphoma (FL) who did not respond or who progressed during or up to six months after treatment with rituximab or a rituximab-containing regimen.

The Group noted:
- obinutuzumab:
  - is only accepted by SMC for relapsed/refractory FL; obinutuzumab is not accepted for use in NHS Scotland for patients with previously untreated advanced FL
  - [for this indication] is given as induction in combination with bendamustine followed by single agent maintenance therapy
  - single agent maintenance therapy is given once every two months for two years or until disease progression (whichever occurs first)
  - [for this indication] meets SMC ultra-orphan criteria, and was accepted for use in NHS Scotland following the output from the PACE process and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of obinutuzumab
- the local estimate of patient numbers is small, but treatment with induction and maintenance represents an additional cost
- the service has experience in the use of obinutuzumab

The Group accepted the restricted local need for obinutuzumab (induction and maintenance) in line with SMC 1219/17, for patients with FL who did not respond or who progressed during or up to six months after treatment with rituximab or a rituximab-containing regimen.

SMC 1219/17 - Obinutuzumab 1,000mg concentrate for solution for infusion (Gazyvaro®) ▼ is routinely available in line with national guidance (SMC 1219/17).

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Indication under review: obinutuzumab in combination with bendamustine followed by obinutuzumab maintenance is indicated for the treatment of patients with follicular lymphoma who did not respond or who progressed during or up to six months after treatment with rituximab or a rituximab-containing regimen.
Obinutuzumab plus bendamustine induction therapy followed by obinutuzumab maintenance significantly increased progression free survival compared with bendamustine monotherapy induction without any maintenance treatment, in patients with rituximab-refractory follicular lymphoma.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of obinutuzumab 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 8a – licensed for hospital use only. Obinutuzumab should be administered under the close supervision of an experienced physician and in an environment where full resuscitation facilities are immediately available. **FTeam**

8.4. FG1SMC 1153/16 - FEBUXOSTAT (PREVENTION OF HYPERURICAEMIA IN TUMOUR LYSIS SYNDROME)

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

The Group considered the submission for febuxostat for the prevention of hyperuricaemia in a subgroup of patients undergoing chemotherapy for haematologic malignancies at intermediate risk of tumour lysis syndrome (TLS).

The Group noted:
- febuxostat is already included on the formulary (80mg and 120mg tablets) as a second-line option for the treatment of chronic hyperuricaemia
- only the 120mg tablets are licensed for the management of TLS
- the submitting company requested that the SMC considers a sub-group of the licence - for the prevention of hyperuricaemia in adult patients at intermediate risk of TLS in whom allopurinol is either unsuitable or contraindicated
- febuxostat is not accepted for use in NHS Scotland for the treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate to high risk of TLS, or for the prevention of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at high risk of TLS
- treatment with febuxostat in patients with ischaemic heart disease or congestive heart failure is not recommended

The Chairman highlighted the unclear cardiovascular risk profile of febuxostat and requested clarification of the measures the service will take to manage the cardiovascular risk profile of febuxostat. **FD**

The Group accepted the restricted local need for febuxostat 120mg tablets, as outlined in SMC 1153/16, for the prevention of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate risk of TLS in whom allopurinol is either unsuitable or contraindicated.

SMC 1153/16 - Febuxostat 120mg film-coated tablet (Adenuric®) is routinely available in line with national guidance (SMC 1153/16).
Indication under review: the prevention of hyperuricaemia in adult patients undergoing chemotherapy for haematologic malignancies at intermediate risk of tumour lysis syndrome in whom allopurinol is either unsuitable or contraindicated, such as:
- **those intolerant of allopurinol**
- **those in whom allopurinol is contraindicated, e.g. patients with renal impairment**

In a phase III, randomised, double-blind study in adults with haematologic malignancies at intermediate to high risk of TLS, febuxostat was significantly superior to a xanthine oxidase inhibitor at reducing serum uric acid levels.
It was classified 1b- available for restricted use under specialist supervision and 8b –

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recommended for hospital use only. Adenuric® should be started two days before the beginning of cytotoxic therapy and continued for a minimum of 7 days; however treatment may be prolonged up to 9 days according to chemotherapy duration as per clinical judgment. **FTeam**

It was reported that rasburicase is used locally and included in guidelines but is not currently noted on the formulary. The Group considered the use of rasburicase as accepted practice. Due to its long-standing use (licensed before SMC established) the Group agreed to record rasburicase on the formulary without the need for a full submission.

Rasburicase 1.5 mg/mL powder and solvent for concentrate for solution for infusion (Fasturtec®) is routinely available in line with local guidance.
Indication under review: treatment and prophylaxis of acute hyperuricaemia, in order to prevent acute renal failure, in adults, children and adolescents (aged 0 to 17 years) with haematological malignancy with a high tumour burden and at risk of a rapid tumour lysis or shrinkage at initiation of chemotherapy. It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. Rasburicase should be administered under the supervision of a physician trained in chemotherapy of haematological malignancies. **FTeam**

8.5. FG1SMC 1246/17 - DEFERASIROX (EXJADE®) ▼ - (CHRONIC IRON OVERLOAD)

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

The Group considered the submission for a new formulation of deferasirox.

It was confirmed that:
- deferasirox is already included on the formulary in line with SMC 347/07 published 2007 - for the treatment of chronic iron overload associated with the treatment of rare acquired or inherited anaemias requiring recurrent blood transfusions (excluding patients with myelodysplastic syndromes (MDS))
- this request would extend use to patients with MDS and recognise the new formulation of deferasirox (film-coated tablets)

The Group noted:
- deferasirox:
  - was previously available as dispersible tablets but is now only available as film-coated tablets
  - [for MDS] would be a second-choice agent used when desferrioxamine is contraindicated or inadequate
  - [for the MDS indication] meets SMC ultra-orphan criteria, and was accepted for use in NHS Scotland following the output from the PACE process and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
  - is an oral treatment option, whereas desferrioxamine is given by slow subcutaneous infusion
  - would be supplied by the hospital
- risk minimisation materials are available for deferasirox

The Group accepted the restricted local need for deferasirox film-coated tablets as outlined in SMC 347/07 published January 2017.

SMC 347/07 and 1246/17 - Deferasirox 90mg, 180mg and 360mg film-coated tablets (Exjade®) ▼ is routinely available in line with national guidance (SMC 347/07).
Indication under review:
- **treatment of chronic iron overload associated with the treatment of rare acquired or inherited anaemias requiring recurrent blood transfusions (SMC 347/07 published February 2007).**
- **treatment of chronic iron overload due to blood transfusions when desferrioxamine therapy is contraindicated or inadequate, in adult and paediatric patients aged 2 years and older with myelodysplastic syndrome and with an International Prognostic Scoring System (IPSS) score of low or intermediate -1**

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risk (SMC 347/07 published January 2017);
Deferasirox film-coated tablets cannot be accepted for use in treatment of chronic iron overload requiring chelation therapy when desferrioxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older as a full submission has not been received by SMC for this indication.
It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be initiated and maintained by physicians experienced in the treatment of chronic iron overload. **FTeam**

8.6. FGASMC 2016 - FLUTICASONE PROPIONATE/FORMOTEROL FUMARATE (FLUTIFORM®) (SEVERE ASTHMA – NEW DEVICE) – DEFERRED TO JANUARY 2019

8.7. FGASMC 2108 - FOSAPREPITANT 150MG POWDER FOR SOLN. FOR INFUSION (IVEMEND®)

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

The Group considered the abbreviated SMC advice for the paediatric extension of fosaprepitant infusion, SMC 2108.

The service has confirmed that as fosaprepitant infusion is not currently included in paediatric guidelines there is no immediate need for this product. However, formulary inclusion would be preferred to prevent delays if a patient were to require treatment, or be transferred from another Board on the infusion.

The Group supported the restricted local need in the paediatric service for fosaprepitant infusion as outlined in SMC 2108.

SMC 2108 - Fosaprepitant 150mg powder for solution for infusion (Ivemend®) is routinely available in line with national guidance (SMC 2108).
Indication under review: prevention of nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in paediatric patients aged 6 months to <18 years.
Fosaprepitant is given as part of a combination therapy.
SMC has previously accepted fosaprepitant as part of combination therapy for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based chemotherapy in adults (678/11).
SMC has previously accepted aprepitant for use as part of combination therapy for the prevention of nausea and vomiting associated with moderately and highly emetogenic cancer chemotherapy in children, toddlers and infants from the age of six months to 17 years (1252/17 and 1241/17 respectively). Intravenous fosaprepitant is a pro-drug of oral aprepitant and it offers an alternative with limited budget impact.
It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only. **FTeam**

8.8. SMC 2113 – BRIVARACETAM (BRIVIACT®) ▼ (REFRACTORY EPILEPSY (PAEDIATRICS))

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

The Group considered the abbreviated SMC advice for the paediatric extension of brivaracetam to include children aged 4 years to less than 16 years of age.

The Group noted:
- brivaracetam
  - is included on the formulary for the same indication for adults and adolescents from 16 years of age - as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in patients with refractory epilepsy
  - is not licensed as monotherapy
  - will be restricted to initiation by or on the advice of physicians experienced in the management of epilepsy

The Group accepted the restricted local need for the paediatric extension (from 4 years to < 16 years of age) of brivaracetam as outlined in SMC 2113.

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	SMC 2113 - Brivaracetam 10mg, 25mg, 75mg, 100mg film-coated tablets; 10mg/mL oral solution; 10mg/mL solution for injection/infusion (Briviact®) ▼ is routinely available in line with national guidance (SMC 2113). **Indication under review: adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in children from 4 years to <16 years of age with refractory epilepsy.** **Restriction: treatment should be initiated by physicians who have appropriate experience in the treatment of epilepsy.** **SMC has previously accepted brivaracetam for restricted use as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy.** **It was classified 1b – available for restricted use under specialist supervision and 8d - treatment may be initiated in the community on recommendation of a consultant/specialist.**	**FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED DECEMBER 2018

The Group noted the SMC provisional advice issued December 2018.

If the negative SMC recommendation is published next month, this medicine will not be included on the formulary for the indication in question. **FTeam**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED DECEMBER 2018

The Group noted the SMC advice published December 2018.

Following publication the non-submission statement for pembrolizumab (Keytruda®) ▼ SMC 2143, this medicine will not be included on the Grampian Joint Formulary for the indication in question. **FTeam**

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

- SMC 2112 - Nivolumab (Opdivo®) ▼ (submission expected)
- SMC 2111 - Ciclosporin (Verkazia®) (submission expected)
- SMC 2119 - Pertuzumab (Perjeta®) (submission expected)
- SMC 2121 - Ocrelizumab (Ocrevus®) ▼ (submission received)

Local advice for these medicines and indications will be included in the December 2018 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTeam**

11. GENERAL INFORMATION FROM SMC DECEMBER 2018

TOCILIZUMAB (ROACTEMRA®) - 162MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE

The paediatric licence extension of tocilizumab for the treatment of active systemic juvenile idiopathic arthritis (sJIA) has been extended to include patients from 1 to 2 years of age. The SMC will not review this licence extension so it will be included on the agenda for discussion at the January meeting. **FTeam**

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Grampian Primary Care Prescribing Group minute October 2018), and 12.2 (Medicines, Guidelines and Policies Group minute September 2018) were noted.

13. **AOCB - NONE**

DATE OF NEXT MEETING

Tuesday 15 January 2019 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE _____ **DATE** **15 January 2019**