NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 15 October 2024 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Miss R Anderson	Dr D Culligan	
Dr V Chieng	Mrs E Milne (Mrs Tiesman attending)	
Ms L Cameron	Mr M Paterson	
Ms A Davie	Mrs S O'Beirne (Miss Anderson deputising)	
Ms F Doney (Vice-Chair)	Dr K Simpson	
Dr L Elliot (Chair)		
Mrs G McKerron		
Mr R Sivewright		
Mrs B Tiesman		

IN ATTENDANCE
Ms Dawn Bruce, Specialist Pharmacy Technician, Formulary Team.

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WELCOME

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

1. APOLOGIES

Apologies for absence were requested and noted.

2. MINUTE AND DECISIONS

2.1. DRAFT MINUTE OF THE MEETING HELD 17 SEPTEMBER 2024

Members accepted the draft note of the meeting subject to minor typographical changes.

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

2.2. FORMULARY GROUP DECISIONS SEPTEMBER 2024 - PUBLISHED 30/09/2024

Members ratified the decisions of the September 2024 meeting as published.

3. MATTERS ARISING

3.1. Action LOG

The action log was noted.

3.2. OLIVE OIL B.P. FOR CRADLE CAP (UPDATE)

Last month members agreed that the formulary should align with NHS Inform and supported removal of olive oil for cradle cap from the formulary and the Pharmacy First Approved List. Publication of the decision was deferred pending confirmation that the position was supported by local Health Visitors.

Mrs McKerron confirmed that the Health Visitor Lead supported aligning to NHS inform and removing olive oil B.P. for cradle cap from the formulary.

Olive oil B.P. is not routinely available as there is a local preference for alternative medicines.
Indication under review: for infantile seborrhoeic dermatitis (cradle cap).
Not routinely available as there is a local preference for alternative medicines. **FTEAM**

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3.3. CARBON FOOTPRINT ICON ON THE FORMULARY (UPDATE)

Ms Doney confirmed that the inhaler sections of the formulary now all include the carbon footprint icons.
Work has also started to include the icons on another NHS Grampian website, the 'Don't Waste a breath' website.

4. PRESENTATION/DISCUSSION

None.

5. NEW PRODUCT REQUESTS

5.1. FG1 464/24 - IVERMECTIN (CHRONIC GASTROINTESTINAL STRONGYLOIDIASIS (ANGUILLULOSIS) AND HUMAN SARCOPTIC SCABIES)

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

The Group considered the request for ivermectin 3mg tablets for the treatment of chronic gastrointestinal strongyloidiasis and the treatment of human sarcoptic scabies.

The Group noted that:

- ivermectin:
  - is an anthelmintic that has been used as an unlicensed product for many years but a licensed 3mg tablet is now available in the UK
  - is a generic product and is considered outwith remit for SMC
- the summary of evidence in the Summary of Product Characteristic (SmPC) is sparse but it does state that treatment with a single ivermectin dose of 200micrograms per kg body weight has been shown to be effective and well-tolerated in patients with normal immunity and in whom infestation by *Strongyloides stercoralis* is restricted to the digestive tract
- a 2014 NICE evidence review of ivermectin for the treatment of scabies showed mixed evidence against the first-choice topical treatment, permethrin, non-inferior for three studies and not as effective for three studies
- in national prescribing guidance ivermectin is recognised as a treatment option for scabies, generally if topical treatments do not resolve symptoms or are difficult to source
- the Primary Care Dermatology Society (PCDS) recommends ivermectin for scabies:
  - if topical treatments have not resolved symptoms and there is evidence of ongoing infestation with the presence of burrow etc.
  - if topical treatments are hard to access/unavailable
  - in conditions where topical treatments may be difficult to apply effectively, e.g., care homes and other circumstances where treatment of a large number of people is required
- crusted scabies (Norwegian scabies) is an uncommon and highly infectious form of scabies, ivermectin is the first-choice agent for crusted scabies
- the local prescribing guidance for scabies is currently under review and Public Health Scotland prescribing guidance is not available

Members accepted that ivermectin has been used, as an imported unlicensed medicine, by local specialists as a treatment for strongyloidiasis and scabies for many years. Members agreed that for the treatment of scabies local practice is that a second dose is given, which is in line with the guidance from the PCDS.

A member highlighted the need for updated local prescribing guidance for scabies, to ensure ivermectin is used appropriately in the relevant patient groups, and that repeated courses of ivermectin are not given without appropriate review. **FTEAM**

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The Group accepted the restricted local need for ivermectin as a treatment option for strongyloidiasis and scabies.

FG1 464/24 - Ivermectin 3mg tablets is routinely available in line with local guidance.
Indication under review treatment of:
- **chronic gastrointestinal strongyloidiasis (anguillulosis)**
- **crusted scabies (Norwegian scabies)**

It was classified 1b - available for restricted use under specialist supervision and 8d - treatment may be initiated in community on the recommendation of a consultant/specialist.
Official guidelines should be taken into consideration. Official guidelines will normally include WHO and public health authorities' guidelines. **FTEAM**

FG1 464/24 - Ivermectin 3mg tablets is routinely available in line with local guidance.
Indication under review: for the treatment of human sarcoptic scabies (excluding crusted scabies). Treatment is justified when the diagnosis of scabies has been established clinically and/or by parasitological examination. Without formal diagnosis treatment is not justified in case of pruritus.
Restriction:
- **if topical treatments have not resolved symptoms and there is evidence of ongoing infestation with the presence of burrow etc.**
- **if topical treatments are hard to access/unavailable**
- **in conditions where topical treatments may be difficult to apply effectively, e.g., care homes and other circumstances where treatment of a large number of people is required**

It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.
Official guidelines should be taken into consideration. Official guidelines will normally include WHO and public health authorities' guidelines. **FTEAM**

5.2. SMC 2592 - SECUKINUMAB (ACTIVE MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA)

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

The Group considered the request for secukinumab for use in adults with active moderate to severe hidradenitis suppurativa (acne inversa) for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment.

The Group noted that:
- secukinumab:
  - [for this indication] is administered by subcutaneous (SC) injection with initial dosing, 300mg weekly for five doses, followed by monthly maintenance dosing. Maintenance dose can be increased to 300mg every 2 weeks.
  - is a monoclonal antibody that binds and neutralises interleukin (IL)-17A. Inhibition of IL-17A reduces the release of pro-inflammatory cytokines, chemokines and mediators of tissue damage, and limits IL-17A-mediated contributions to inflammatory diseases such as hidradenitis suppurativa.
- other biologics included on the formulary for hidradenitis suppurativa are adalimumab (licensed for adolescents and adults from 12 years) and infliximab (off-label use, adults)
- other medical therapy approaches include managing symptoms with antiseptic washes, steroid injections, topical and oral antibiotics such as tetracyclines or clindamycin with rifampicin, retinoids, dapsone, and oral immunomodulators. Surgical procedures range from incision and drainage for acute flares, narrow margin excision

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and extensive excision.
- treatment guidelines for hidradenitis suppurativa are available from the British Association of Dermatologists (BAD) and the PCDS
- evidence comes from two studies involving 1,084 adults with moderate to severe hidradenitis suppurativa, 44% of patients who were given secukinumab achieved at least 50% reduction in abscesses and nodules after 16 weeks, without any increase in the number of abscesses or fistulas, versus 32% of patients given placebo who achieved this response. (ref EMA)
- in the studies secukinumab was given every four weeks, however secukinumab is licensed as 'monthly' dosing
- limitations of the data:
  - no direct evidence against an active comparator
  - short-term efficacy data (16 weeks) for a potentially long-term treatment option. Data up to 52 weeks was presented as observations with no control groups.
  - people with severe hidradenitis suppurativa were excluded from the studies
  - the dose-response for secukinumab is unclear [the SmPC states that people should not be started at the higher dose (300mg every 2 weeks)]
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of secukinumab for this indication

Members agreed that there is an unmet need for effective therapies for people with hidradenitis suppurativa. However, noting the short-term efficacy data (16 weeks) and the unclear secukinumab dose-response, members queried what (and when) stopping rules would be applied, and how often people with hidradenitis suppurativa are reviewed during treatment. **FTEAM**

The Group accepted the restricted local need for secukinumab for use in adults with active moderate to severe hidradenitis suppurativa for whom adalimumab is contraindicated or otherwise unsuitable, as outlined in SMC 2592.

SMC 2592 - Secukinumab 150mg, 300mg solution for injection in pre-filled pen or pre-filled syringe (Cosentyx®) is routinely available in line with national guidance (SMC 2592).
Indication under review: for use in adults with active moderate to severe hidradenitis suppurativa (acne inversa) for whom adalimumab is contraindicated or otherwise unsuitable, including those who have failed to respond or have lost response to prior adalimumab treatment.
In two phase III studies in patients with moderate to severe HS, the proportion of patients who achieved a clinical response (defined as at least a 50% decrease in abscess and inflammatory nodule [AN] count with no increase in the number of abscesses and/or in the number of draining fistulae) was significantly increased with secukinumab (every two weeks) compared with placebo.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/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.
For use under the guidance and supervision of a physician experienced in the diagnosis and treatment of hidradenitis suppurativa. **FTEAM**

5.3. SMC 2610 - RITLECITINIB (SEVERE ALOPECIA IN ADULTS AND ADOLESCENTS)

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

The Group considered the request for ritlecitinib for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older.

The Group noted that:

- alopecia areata is a chronic immune-mediated disorder leading to non-scarring hair loss, primarily affecting the scalp but potentially involving other areas like eyebrows and body hair. The three main types of alopecia areata are patchy with localised hairless areas, alopecia totalis (AT) that is complete scalp hair loss, and alopecia universalis (AU) that is loss of all body hair. Spontaneous hair regrowth is common, multiple disease episodes are typical, and 10 to 25% of patients progress to AT or AU. The condition carries a significant psychological burden, and the treatment goal is to achieve lasting hair regrowth with an acceptable appearance from the patient's viewpoint. (ref SMC)
- in people with alopecia areata, the immune system attacks the hair follicles and causes hair growth to slow or stop altogether, leading to hair loss
- ritlecitinib:
  - blocks the action of Janus kinase (JAK) 3 and the tyrosine kinase enzymes which play an important role in inflammation. By blocking these enzymes, ritlecitinib reduces inflammation, allowing hair regrowth in people with alopecia areata. The full pathophysiology is still not understood.
  - [for this indication] was accepted for use in NHS Scotland following a full submission
- there are very few licensed treatment options for people with alopecia areata. Baricitinib, a JAK inhibitor, is licensed for alopecia areata but not recommended for use in NHS Scotland, SMC 2572.
- a draft local treatment pathway is included with the request and national guidance is available from NICE Clinical Knowledge Summaries, BAD and the PCDS
- the benefits of ritlecitinib were investigated in a main study involving 718 adults and adolescents over 12 years of age with severe alopecia areata, 261 of whom were given 50mg ritlecitinib or placebo. All patients had more than 50% hair loss on the scalp before they started treatment.
  After 24 weeks of treatment, disease symptoms improved in patients given ritlecitinib: 13% of them were in near remission, meaning that they had more than 90% hair coverage on their scalp, and 23% had more than 80% hair coverage. Such improvements were seen in 1.5% of patients given placebo.
  After 48 weeks, 31% of patients given ritlecitinib were in near remission. When asked whether their alopecia had improved, 49% of patients given ritlecitinib stated that their condition had moderately or greatly improved, compared with 9% of patients given placebo. Ref EMA
- NICE TA958 noted that - *There is no standard treatment for severe alopecia areata, and access to treatment varies widely. Hair loss can cause severe psychological distress*.
  Evidence from clinical trials shows that ritlecitinib is more effective than placebo at improving hair regrowth for up to 24 weeks.
  The most likely cost-effectiveness estimates are within the range that NICE considers an acceptable use of NHS resources. So, ritlecitinib is recommended.
- limitations of the data:
  - from the study, the quality of life (QoL) outcomes remain uncertain (study did not demonstrate meaningful differences). However, the BAD challenged this stating that EQ5D is not an appropriate measure of QoL impairment in alopecia areata, as EQ5D often fails to capture quality-of-life improvements for people with skin conditions.
  - limited data for a potentially long-term treatment, longer-term effectiveness unknown
  - limited data on the impact of interrupting treatment in responders
  - unclear if effective in AT/AU – low patient numbers and trial not designed to test subgroups
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of ritlecitinib

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Members acknowledged that hair loss can cause severe psychological distress, and questioned if people that had stopped treatment due to response would be retreated? **FTEAM**
Members noted the monitoring requirements and requested clarification that monitoring would be undertaken by the managed service, in clinic and/or at Secondary Care community-hubs. **FTEAM**

The Group accepted the restricted local need for ritlecitinib for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older.

SMC 2610 - Ritlecitinib 50mg hard capsules (Litfulo®) ▼ is routinely available in line with national guidance (SMC 2610).
Indication under review: for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older.
In a randomised, double-blind, phase IIb/III study in patients with severe alopecia areata, ritlecitinib was associated with statistically significant improvements in scalp hair regrowth versus placebo at week 24.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by a healthcare professional experienced in the diagnosis and treatment of alopecia areata. **FTEAM**

5.4. FG1 451/22 - ATOVAQUONE AND PENTAMIDINE ISETHIONATE (OFF-LABEL FOR THE PREVENTION OF *PNEUMOCYSTIS JIROVECII* PNEUMONIA)

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

The Group considered the request for the off-label use of atovaquone oral solution as an alternative second-line treatment option for the prevention of *Pneumocystis jirovecii* pneumonia (PJP) in adults for whom co-trimoxazole is not effective, not tolerated or contraindicated.

The Group noted that:
- *Pneumocystis* pneumonia is a life-threatening disease in immunocompromised patients
- co-trimoxazole is the preferred first-choice agent for the prevention of *Pneumocystis* infections
- the European Conference on Infections in Leukaemia (ECIL) guidelines for patients' with haematological malignancy and stem cell transplant recipients support the use of atovaquone [and pentamidine by inhalation or intravenously] as a second-line option in this setting
- locally pentamidine is already used by inhalation for this indication. It requires nebuliser treatment every four weeks in hospital, and due to its potential toxicity it can only be administered by trained staff in a specific isolated and ventilated room.
- atovaquone is an oral treatment option that patients could take at home, so providing the opportunity to move treatment closer to home
- atovaquone is included on the Greater Glasgow and Clyde formulary as an alternate second-line choice for the prevention of PJP
- treatment would be initiated and monitored by the managed service, but supply by Primary Care was requested
- the requestor stated that there are an increasing number of situations where PJP prophylaxis is required for Haematology patients, and the service cannot support pentamidine for every person that cannot receive co-trimoxazole

Members noted that treatment would be initiated and monitored by the managed service,

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but did not support prescribing by Primary Care. Members considered prescribing by the use of hospital-based prescription stationery or by the Secondary Care community-hubs would be more appropriate.

The Group accepted the restricted local need for atovaquone liquid and aerosolised pentamidine as second-line treatment options for the prevention of *Pneumocystis jirovecii* pneumonia in adults. Prescribing should remain within the managed service for the entire course of treatment.

FG1 451/22 - Atovaquone 750mg/5mL oral suspension is routinely available in line with local guidance.
Indication under review: [off-label use] as a second-line treatment option for the prevention of *Pneumocystis jirovecii* pneumonia in adults for whom co-trimoxazole is not effective, not tolerated or contraindicated.
Restriction: prescribing restricted to the haematology service.
It was classified 3b - licensed product requested for unlicensed use and 8b - recommended for hospital use only. **FTEAM**
Note: The classification 'recommended for hospital use only' does not prevent supply of medicines by Primary Care, e.g. use of hospital-based prescription (HBP) stationery.

FG1 451/22 - Pentamidine isethionate 300mg powder for solution for injection/infusion is routinely available in line with local guidance.
Indication under review: [unlicensed route/off-label use] by inhalation as a second-line treatment option for the prevention of *Pneumocystis jirovecii* pneumonia in adults for whom co-trimoxazole is not effective, not tolerated or contraindicated.
Restriction: prescribing restricted to the haematology service.
It was classified 3b - licensed product requested for unlicensed use and 8b - recommended for hospital use only. **FTEAM**

6. FORMULARY REVIEW

6.1. VOXELOTOR (OXBRYTA®) MARKETING AUTHORISATION WITHDRAWN

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

Ms Doney reported that Pfizer in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) has withdrawn voxelotor from the UK market as a precautionary measure while a review of the benefits and risks is carried out.
The local formulary submission has been halted.

Members supported update of the formulary entry to note the precautionary withdrawal. **FTEAM**

6.2. PREFERRED BRANDS/PRODUCTS WITHIN THE MANAGED SERVICE

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

Ms Doney confirmed that:
- ustekinumab is now off patent and available as biosimilar products
- a NHSS contract for biosimilar ustekinumab came into effect from 1 October 2024
- ustekinumab is used by several specialities, Dermatology, Gastroenterology and Rheumatology
- the originator product, Stelara®, was accepted by SMC for use in the treatment of psoriasis, psoriatic arthritis, severely active Crohn's disease and severely active ulcerative colitis
- an efficiency is available from the introduction of biosimilar ustekinumab
- NHS Grampian's biosimilar of choice for ustekinumab is Wezenla® and supply via a homecare arrangement is expected

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The Group supported the addition of biosimilar ustekinumab to formulary without the need for a full submission.

Ustekinumab 130mg/26mL concentrate for solution for infusion, 45mg/0.5mL solution for injection vials, 45mg/0.5mL, 90mg/1mL solution for injection in pre-filled syringe (Wezenla®) is routinely available in line with local guidance.
Indication under review: in line with the current SMC and Healthcare Improvement Scotland advice for the reference ustekinumab product [Stelara®].
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Wezenla® is intended for use under the guidance and supervision of physicians experienced in the diagnosis and treatment of conditions for which Wezenla® is indicated. **FTEAM**

6.3. ARTIFICIAL SALIVA (FEEDBACK FROM PALLIATIVE CARE PHARMACIST)

At the September meeting, members noted the discontinuation of Glandosane® leaving Biotene Oralbalance® dry mouth saliva replacement gel as the only formulary product.

Ms Doney confirmed that Palliative Care recommends BioXtra® Dry Mouth Gel Mouthspray, and that BioXtra® Dry Mouth Gel Mouthspray costs less than Glandosane®.

The Palliative Care pharmacist confirmed that there is a Grampian-wide short life working group reviewing mouth care, including these products, and an update will be provided when recommendations are made. **ADUN**

The Group supported including BioXtra® Dry Mouth Gel Mouthspray on the formulary, as an additional treatment option for the symptomatic treatment of dry mouth, without the need for a full submission.

BioXtra® Dry Mouth Gel Mouthspray is routinely available in line with local guidance.
Indication under review: children and adults for the symptomatic treatment of dry mouth.
It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care. **FTEAM**

6.4. SUCRALFATE (REQUEST TO REINSTATE ON FORMULARY)

Ms Doney reported that:
- previously sucralfate tablets and suspension were included on the formulary, mainly for use in the Intensive Therapy Unit (ITU) and patients undergoing radiotherapy of the mouth and throat
- there were supply issues and products discontinued, so in 2015 sucralfate was not moved over to the new formulary platform
- the Gastroenterology Service is requesting that sucralfate is reinstated on the formulary for the previous indications and potentially new indications

Members discussed the request to reinstate sucralfate on the formulary without a submission, however with the change in the cost base and additional use being considered, members rejected the request for reinstatement of the previous advice and advised that a full submission should be progressed. **FTEAM**

6.5. FINERENONE (UPDATE)

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

Finerenone, for diabetic kidney disease (DKD), was discussed at the May 2024 meeting

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when members requested that, to support introduction, a prescribing protocol was produced and approved by the Medicine Guidelines and Policies Group (MGPG). Until the prescribing protocol was approved finerenone was classified on the formulary as RED (hospital-only).

Ms Doney confirmed that the MGPG approved the finerenone protocol at its October meeting and the protocol will be distributed soon.

The Group accepted the reclassification of finerenone to allow prescribing in Primary Care. Prescribing should remain with the specialist service until the patient is on a stable dose and initial monitoring (initiation and at least first monitoring at 4 weeks) is completed and appropriate to handover to Primary Care.

SMC 2486 - Finerenone 10mg, 20mg film-coated tablets (Kerendia®) ▼ is routinely available in line with local guidance.
Indication under review: for the treatment of chronic kidney disease (stage 3 and 4 with albuminuria) associated with type 2 diabetes in adults.
Restriction: as add-on to optimised standard care; this should include, unless they are unsuitable, the highest tolerated licensed doses of:

- **angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs) and**
- **sodium–glucose cotransporter-2 (SGLT2) inhibitors**

In a randomised, double-blind, phase III study, the addition of finerenone to angiotensin converting enzyme inhibitor or angiotensin receptor blocker reduced the risk of the primary composite renal outcome comprising kidney failure, a sustained decrease in estimated glomerular filtration rate of ≥40% or death from renal causes compared with placebo.
It was classified 1b- available for restricted use under specialist supervision and 8c - treatment to be initiated in hospital prior to handover. **FTEAM**

6.6. OCRELIZUMAB (NEW FORMULATION OF CURRENT FORMULARY PRODUCT)

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

Ms Doney reported that:

- a new SC formulation of an existing formulary drug, ocrelizumab, is now available
- the new formulation is considered outwith remit for the SMC
- ocrelizumab 300mg concentrate for solution for infusion is included on the formulary in line with the recommendations of the SMC for adults with:
  - relapsing remitting multiple sclerosis (RRMS), SMC 2121
  - early primary progressive multiple sclerosis (PPMS), SMC 2223
- ocrelizumab SC is administered:
  - at a dose of 920mg every 6 months. A minimum interval of 5 months should be maintained between each dose
  - in approximately 10 minutes compared with an infusion time of 2 to 3.5 hours (not including the first dose which is split into two infusions)
- for the SC preparation no division of the initial dose or subsequent doses into separate administrations is required
- patients may start treatment using SC or intravenous ocrelizumab. Patients currently receiving intravenous ocrelizumab may continue treatment or transition to the SC preparation.
- studies:
  - provided evidence of non-inferiority of ocrelizumab 920mg SC compared to 600mg intravenous [demonstrated based on the pharmacokinetic primary endpoint, area under the curve up to week 12 (AUCw1-12) post-injection]
  - showed that ocrelizumab significantly suppressed relapses, sub-clinical disease activity measured by MRI, and disease progression compared with interferon beta-

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1a 44microgram subcutaneous
- formulary inclusion would be cost neutral for drug costs, and provides the opportunity for significant time saving for staff and patients
- the SC formulation could be supplied by a homecare arrangement which could reduce trips to the hospital - moving treatment closer to home
- December 2018, when the SMC advice for RRMS was published, ocrelizumab was restricted to adults with active disease defined by clinical or imaging features who are contra-indicated or otherwise unsuitable for alemtuzumab.
  In 2019, following a safety review, alemtuzumab was restricted to only be used to treat RRMS if the disease was highly active despite treatment with at least one disease-modifying therapy or if the disease is worsening rapidly.

Members accepted that it was not appropriate to restrict ocrelizumab to people who are contra-indicated or otherwise unsuitable for alemtuzumab.

A member queried the level of service provided by the homecare arrangement and if it included a nursing component. If there was not a nursing component confirmation was requested that nurses in Primary Care would not be required to support administration of the injection. **FTEAM**

The Group accepted the restricted local need for the new SC formulation of ocrelizumab.

Ocrelizumab 920mg solution for injection, 300mg concentrate for solution for infusion (Ocrevus®) is routinely available in line with local guidance.
Indications under review: for the treatment of:
- **relapsing remitting multiple sclerosis (RRMS) in adults with active disease defined by clinical or imaging features**
- **adults with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity**

This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.
Treatment should be initiated and supervised by specialised physicians experienced in the diagnosis and treatment of neurological conditions. **FTEAM**

6.7. FOR DISCUSSION – SHOULD THE FORMULARY INCLUDE WARNINGS RE PRODUCTS CONTAINING SOYA OR PEANUTS

Ms Doney reported that the Formulary Team had received an email from a colleague in Primary Care requesting consideration of noting products that included peanuts or soya on the formulary.

Members discussed the request but noted:
- that these are just two potential food allergies, what about other potential allergens, e.g. eggs, what would be included or excluded and why?
- changes to ingredients/excipients can happen often, so regular checks would be required. Generic products can have several manufacturers, each SmPC would have to be checked.
- if taken forward, there is a risk that if a note was not included against a product then people would assume that there were no allergens of concern in the product

The Medication Safety Advisor reported that previous Safety Notices considered the risk of prescribing to people with food allergies, and the most recent SmPC or Patient Information Leaflet (PIL) for a medicine were considered appropriate resources to identify

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potential allergens.

The Group considered that a significant amount of time would be required to ensure the formulary entries were accurate and up-to-date, and did not support the request to note food allergens against formulary entries. **FTEAM**

7. PUBLISHED ADVICE

7.1. SCOTTISH MEDICINES CONSORTIUM ADVICE PUBLISHED OCTOBER 2024

The Group noted the SMC advice published October 2024.

Following publication of the non-submission statements, for cemiplimab (Libtayo®)▼ SMC 2724, drospirenone (Slynd®) SMC 2725 and nivolumab (Opdivo®) SMC 2726, these medicines 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 2685 faricimab (Vabysmo®)▼
- SMC 2689 pembrolizumab (Keytruda®) (submission expected)
- SMC 2678 relugolix (Orgovyx®)▼
- SMC 2659 rezafungin acetate (Rezzayo®)▼ (submission expected)
- SMC 2673 selinexor (Nexpovio®)▼
- SMC 2674 selinexor (Nexpovio®)▼ (submission expected)

Local advice for these medicines and indications will be included in the October 2024 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

8. PROVISIONAL ADVICE

8.1. SCOTTISH MEDICINES CONSORTIUM ADVICE ISSUED OCTOBER 2024

The Group noted the SMC provisional advice issued October 2024.

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

9. OTHER BUSINESS

9.1. SMC VISITING ADTCS

The Chair reminded members that Dr Scott Muir and Dr Yvonne Semple (Chair and Vice-Chair) are scheduled to attend the November Grampian Area Drug and Therapeutics Committee (GADTC) to update on the work of the SMC, enable discussion around issues of common interest and receive feedback on how SMC can further collaborate with ADTCs.

Formulary Group members are welcome to join the meeting for the presentation and discussion, members that wish to join the meeting should email Ms Doney. **ALL**

10. DOCUMENTS FOR INFORMATION

Items 10.1 (Drug Safety Update September 2024), 10.2 (Flash report – Wound Formulary Group), 10.3 (MHRA launched a new three-year Strategy for Improving Safety) and 10.4 (RCGP RPS Repeat Prescribing Toolkit) were noted.

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11. AOCB

BHIVA RAPID GUIDANCE ON THE USE OF STATINS FOR PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE IN PEOPLE LIVING WITH HIV V2 (MARCH 2024)

Members discussed the British HIV Association (BHIVA) guidance on the use of statins for primary prevention of cardiovascular disease in people living with HIV.

Members supported the use of statins for primary prevention in line with current guidance (SIGN). However, members highlighted there are different treatment thresholds for NHS England (NICE) and NHS Scotland (SIGN), and that the BHIVA guidance reduced the estimated 10-year cardiovascular disease risk level to 5% or greater, which is significantly lower than SIGN.
Concerns were raised about the equity of this positon, as people living with HIV are not the only patient group at a greater risk of atherosclerotic cardiovascular disease.

Members considered that the Formulary Group was not the correct forum for discussion about the primary prevention level for people living in NHS Grampian. The question will be escalated to the Grampian Area Drug and Therapeutics Committee (GADTC) to consider the way forward. **FTEAM**

DATE OF NEXT MEETING

Tuesday 19 November 2024 starting at 14.30 via Microsoft Teams

Signature on file

CHAIR'S SIGNATURE **Dr Louise Elliot** **DATE 19 NOVEMBER 2024**