

**NHS GRAMPIAN**  
**Minute of Formulary Group Meeting**  
**Tuesday 21 January 2020 at 14:30 in the Seminar Room, David Anderson Building**

**PRESENT**

Ms A Davie  
Ms F Doney  
Dr L Elliot  
Dr J Fitton  
Ms M Galvin  
Professor J McLay (Chairman)  
Mrs L Montgomery  
Mr M Paterson  
Mr R Sivewright (until item 9)

**APOLOGIES**

Mrs L Harper  
Dr A MacDonald  
Dr W Moore  
Mr C Rore  
Dr A Sun

**APPROVED**

**IN ATTENDANCE**

Dr Alexander Bonsall, Dermatology Consultant, for items 8.1 to 8.3  
Dr Mihaela-lulia Mihaescu, Dermatology Consultant, for items 8.1 to 8.3  
Ms Caitlin Wilkinson, Formulary Team administrator

Note some items were taken outwith the agenda running order.

**ITEM SUBJECT**

**ACTION**

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

The Chairman reminded members that to assist preparation of the meeting note and ensure decisions are accurately recorded the meeting would be digitally recorded. When the minute is "approved" the relevant MP3 file will be deleted.

Members consented to recording the meeting.

**3. PRESENTATION – BIOLOGIC AGENTS FOR PLAQUE PSORIASIS**

Dr Alexandra Bonsall, Consultant Dermatologist, and Dr Mihaela-lulia Mihaescu, Locum Consultant Dermatologist, attended the meeting to provide the Group with an update on the use of three biologic agents recently licensed for psoriasis.

Dr Bonsall provided the Group with an informative presentation on two newly licensed injectable biologics for psoriasis.

Dr Bonsall confirmed that:

- tildrakizumab and rizankizumab are interleukin-inhibitors (IL-inhibitors). They target the IL23 specific P19 subunit and are more skin specific in their action.
- the most commonly reported side-effect in the trials were upper respiratory tract infections, and no new safety signals were seen
- both agents are self-administered by subcutaneous (SC) injection and should be avoided in pregnancy and breast feeding
- although the drugs currently in use are effective, the newer biologic agents are more targeted for skin conditions
- risankizumab:
  - is a humanised monoclonal antibody
  - shows consistent response regardless of previous biologic history
  - is administered by subcutaneous injection at week 0, week 4 and every 12 weeks thereafter, with criteria to stop treatment if no response at 16 weeks
  - common side-effects include asthenia, headaches, infection and itch
  - is effective for treating psoriasis affecting the scalp, nails, hands and feet
- tildrakizumab
  - is a recombinant human monoclonal antibody
  - is administered by subcutaneous injection [100mg] at week 0, week 4 and every

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	12 weeks thereafter	
	<ul style="list-style-type: none"><li>• is slower acting so has stopping criteria if no response at 28 weeks</li><li>• the dose can be increased to 200mg if there is a higher disease burden or if the patient's weight is greater than 90kg</li><li>• common side-effects include back pain, diarrhoea, headache, risk of infection and nausea</li></ul>	

Dr Mihaescu confirmed that:

- certolizumab:
  - is an TNF alpha inhibitor, recently licensed as a treatment option for psoriasis, however it has been licensed for rheumatological conditions for much longer
  - is the only biologic agent with data to show that it does not cross the placenta, making it the drug of choice for pregnant women or those planning pregnancy
  - is not present in breast milk

Drs Bonsall and Mihaescu confirmed that:

- [for dermatological conditions] there are currently three TNF alpha inhibitors [adalimumab, etanercept and infliximab] and one IL-23 inhibitor [guselkumab] on the formulary
- there is an expectation that the new agents will be included on the British Association of Dermatologists Biologic Interventions Register (BADBIR\*), and the Dermatology Service would promote use of agents that are included on the register
- the British Association of Dermatologists (BAD) guidelines for biologic therapy for psoriasis are currently being updated, and the service follows the BAD guidelines
- there are objective and subjective criteria for considering prescribing a biologic and the BAD biologic guideline encourages tailoring treatment to the patient
- there is no head-to-head data for the biologic agents
- biological therapies, even agents within the same drugs class, have different affinities, side-effect profiles, and durations of action, so limiting the number of formulary agents within a drug class would be disadvantageous for patients
- patient numbers are expected to be small, but will be cumulative and patients will move through the biologic agents with time
- certolizumab would not be considered first-line for all women of child-bearing age, to ensure its effect is not exhausted by the time a woman becomes pregnant or wishes to plan a pregnancy

The Chairman thanked Dr Bonsall and Dr Mihaescu for attending the meeting, and Drs Bonsall and Mihaescu left the meeting before decision-making.

Items 8.1 to 8.3 were taken together.

**8.1. FG1SMC 2132 – CERTOLIZUMAB (MODERATE TO SEVERE PLAQUE PSORIASIS)**

**8.2. FG1SMC 2196 – RISANKIZUMAB (MODERATE TO SEVERE PLAQUE PSORIASIS)**

**8.3. FG1SMC 2167 – TILDRAKIZUMAB (MODERATE TO SEVERE PLAQUE PSORIASIS)**

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

The Group discussed the submissions for certolizumab, risankizumab and tildrakizumab for the management of plaque psoriasis in adults.

The Group noted that:

- there are nationally agreed homecare arrangements available for the three biologic agents

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\* BADBIR is a clinical study to monitor the long-term safety of drugs used to treat psoriasis.

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	<ul style="list-style-type: none"><li>• the BAD biologics guideline for psoriasis is currently under review with publication expected this year</li><li>• patient numbers are expected to be small. There are no patients waiting for the newer IL-23 inhibitors, however certolizumab would be accessed earlier [for women planning pregnancy or currently pregnant]</li><li>• risankizumab and tildrakizumab offer a less frequent dosing schedule [every 12 weeks] which is advantageous to patients</li><li>• tildrakizumab is only the second agent to allow dose increase for patients [over 90kg]</li><li>• the cost-effectiveness of the three biologic therapies is improved by the availability of Patient Access Schemes</li></ul>	
	<p>The Group accepted the restricted local need for certolizumab for the treatment of adults with moderate to severe plaque psoriasis in adults, as outlined in SMC 2132.</p>	
	<p><b>SMC 2132 - Certolizumab pegol 200mg solution for injection in pre-filled syringe and pen (Cimzia®) is routinely available in line with national guidance (SMC 2132). Indication under review: for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Restriction: patients who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contraindication to these treatments. Certolizumab pegol has shown a similar reduction in the signs and symptoms of psoriasis in adults with moderate to severe plaque psoriasis compared with another tumour necrosis factor (TNF) antagonist. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of certolizumab pegol 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 should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of psoriasis. Patients should be given the special reminder card.</b></p>	FTeam
	<p>The Group accepted the restricted local need for risankizumab for the treatment of adults with moderate to severe plaque psoriasis, as outlined in SMC 2196.</p>	
	<p><b>SMC 2196 - Risankizumab 75mg solution for injection in pre-filled syringe (Skyrizi®) ▼ is routinely available in line with national guidance (SMC 2196). Indication under review: for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Restriction: for patients who have failed to respond to conventional systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contraindication to these treatments. Risankizumab was superior to placebo, a tumour necrosis factor antagonist, and an interleukin 12/23 antagonist in improving symptoms of adult patients with moderate to severe plaque psoriasis. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of risankizumab and is contingent upon the continuing availability of the patient access scheme, or a list price that is equivalent or lower, in NHS Scotland. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Skyrizi® is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of psoriasis.</b></p>	FTeam

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	<p>The Group accepted the restricted local need for tildrakizumab for the treatment of adults with moderate to severe plaque psoriasis, as outlined in SMC 2167.</p> <p><b>SMC 2167 – Tildrakizumab 100mg solution for injection in prefilled syringe (Ilumetri®) ▼ is routinely available in line with national guidance (SMC 2167). Indication under review: for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Restriction: for use in patients who have failed to respond to conventional systemic therapies (including ciclosporin, methotrexate and phototherapy), are intolerant to, or have a contraindication to these treatments. Tildrakizumab was superior to placebo in improving the signs and symptoms of psoriasis in adults with moderate to severe plaque psoriasis, who were candidates for systemic therapy. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tildrakizumab 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. Ilumetri® is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of plaque psoriasis.</b></p>	<p><b>FTeam</b></p>
<b>1.</b>	<p><b>APOLOGIES</b></p> <p>Apologies for absence were requested and noted.</p>	
<b>2.</b>	<p><b>DRAFT MINUTE OF THE MEETING HELD 19 NOVEMBER 2019 AND 17 DECEMBER 2019</b></p> <p>The Group accepted the draft note of the November meeting subject to minor typographical changes, and clarification of the third paragraph on page 7.</p> <p>The Group accepted the draft note of the December meeting subject to minor typographical changes.</p> <p>The corrected final approved minutes will be in the public domain within 21 days of approval.</p>	<p><b>FD</b></p>
<b>4.</b>	<p><b>MATTERS ARISING</b></p> <p><b>4.1. ACTION LOG</b></p> <p>The Action log was noted.</p> <p><b>4.2. FG1 400/17(2) - CINACALCET (REDUCTION OF HYPERCALCAEMIA IN ADULT PATIENTS WITH PRIMARY HYPERPARATHYROIDISM) – UPDATE</b></p> <p>At the December 2019 meeting, the Group was minded to accept cinacalcet for the reduction of hypercalcaemia in adult patients with primary hyperparathyroidism (HPT). The Group requested clarification of the patient group that cinacalcet will potentially benefit and for a summary of the individual patient requests [for cinacalcet].</p> <p>The Group considered Dr Abraham's email response, noting that:</p> <ul style="list-style-type: none"><li>the indication/patient group and calcium levels used are similar to the NICE guidance released in May 2019. However patients with an adjusted calcium level between 2.85mmol/litre and 3.0mmol/litre, would only be considered for prescribing after a clinical review by a Consultant Endocrinologist [in clinic]. Patients with calcium levels above 3.0mmol/litre could be prescribed cinacalcet tablets on the advice of a Consultant Endocrinologist.</li><li>the summary of the individual patient requests showed a small number of patients</li></ul>	

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
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that would align with the recommended patient group. The average daily dose of cinacalcet was 90mg, and normocalcaemia was achieved for all patients

Ms Doney confirmed that review of PRISMS data generally supported the information provided by Dr Abraham. However, there may be some off-label dose recommendations, and although dose fluctuations appeared minimal, the dosing instructions printed on prescriptions may not reflect what patients were taking.

The Group noted:

- cinacalcet is already included on the formulary for the treatment of secondary hyperparathyroidism with end-stage renal disease (ESRD), however prescribing is limited to hospital only
- there is the potential for inequity in the system if one service accesses prescribing from General Practice whilst another service provides hospital-based prescriptions
- renal patients have their bloods checked when attending for dialysis
- there is a risk of confusion with the different dosing regimens for the two licensed indications – once-a-day dosing for secondary hyperparathyroidism, twice a day dosing for primary HPT
- the cost of treatment for secondary hyperparathyroidism in ESRD ranges from ~ £1,600.00 - £9,000.00 per year whereas primary HPT would range from ~ £3,000.00 - £18,000.00 per year
- [for this indication] there is a risk of prescribing creeping into other service areas
- the local guidance, 'Responsibility for Prescribing Across Secondary and Primary Care,' provides a framework for requesting transfer of prescribing/monitoring of medicines by Primary Care colleagues

The Group noted the small number of patients accessing treatment in the last few years and agreed that there is a need for specialist management by the Endocrinology Service. The Group recognised the potential inequity of supply and agreed that prescribing should be limited to 'hospital only' until there is agreement from Primary Care to accept the prescribing (and monitoring) of cinacalcet.

The Group felt it was reasonable to suppose that the cost-effectiveness of cinacalcet in the restricted group of patients with primary HPT would improve if treatment avoided hospital admission.

The Group accepted the restricted local need for cinacalcet for adults with proven primary HPT in whom parathyroidectomy is not clinically appropriate or is contraindicated, and for adults who have had unsuccessful surgery for primary HPT, prescribing is restricted to hospital prescribing only on the advice of a Consultant Endocrinologist.

**FG1 400/17(2) – Cinacalcet 30mg, 60mg, 90mg film-coated tablets (Mimpara®) is routinely available in line with local guidance.**  
**Indication under review: for the reduction of hypercalcaemia in adult patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated.**  
**It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Prescribing is restricted to hospital and only on the advice of a Consultant Endocrinologists.**

**FTeam**

The Group noted that cinacalcet is also available as Mimpara® granules in capsules for opening. However the European public assessment reports (EPAR) for this formulation considers that *“the current product is still poorly designed and not patient friendly. Replacing the off-label use of crushed tablets with a poorly designed alternative is not considered an improvement. Therefore, the benefit/risk remains negative”*.

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ITEM	SUBJECT	ACTION
	<p>Additionally, at maximum dose 12 capsules will be taken daily; which is a significant pill burden for patients/carers, and there is a potential for non-compliance at higher doses.</p> <p>In view of the negative comments in the EPAR and the lack of a SMC appraisal [for this formulation] the Group agreed that cinacalcet granules in capsules for opening should not be included on the formulary.</p> <p><b>Cinacalcet 1mg, 2.5mg, 5mg granules in capsules for opening (Mimpara®) is not routinely available in NHS Grampian.</b></p> <p><b>Indications under review: as licensed for:</b></p> <ul style="list-style-type: none"><li>• <b>Secondary hyperparathyroidism:</b><ul style="list-style-type: none"><li>• Treatment of secondary hyperparathyroidism (HPT) in adult patients with end-stage renal disease (ESRD) on maintenance dialysis therapy.</li><li>• Treatment of secondary hyperparathyroidism (HPT) in children aged 3 years and older with end-stage renal disease (ESRD) on maintenance dialysis therapy in whom secondary HPT is not adequately controlled with standard of care therapy.</li></ul></li><li>• <b>Parathyroid carcinoma and primary hyperparathyroidism in adults.</b></li></ul> <p><b>Not recommended for use in NHS Grampian.</b></p>	<p><b>FTeam</b></p>
5.	<p><b>FORMULARY GROUP DECISIONS DECEMBER 2019 – PUBLISHED 30/12/2019</b></p> <p>Members ratified the decisions of the December 2019 meeting as published.</p>	
6.	<p><b>NETFORMULARY/FORMULARY REVIEW</b></p> <p><b>6.1. ACICLOVIR 3% EYE OINTMENT – NEW PREPARATION</b></p> <p>There were no declarations of interest recorded in relation to this product.</p> <p>The Group discussed the SBAR submitted regarding the availability of a new licensed aciclovir 3% eye ointment, Aciclovir Agepha 30mg/g eye ointment.</p> <p>Ms Doney confirmed that:</p> <ul style="list-style-type: none"><li>• colleagues in ophthalmology, paediatrics and the Antimicrobial Management Team (AMT) were consulted during the preparation of the SBAR</li><li>• review of PRISMs data showed that in Primary Care most topical aciclovir eye ointment was prescribed for adults, and prescribing for under 18 years was limited</li><li>• restricted use is suggested and the AMT are supportive of the recommendation</li><li>• the newly licensed product has a list price of £45.00/4.5g, which is a four-fold increase compared to the previous product</li></ul> <p>The Group agreed that Aciclovir Agepha 30mg/g eye ointment should be available as a first-line topical agent for children and adolescents, and as a second-line topical agent for adults on the advice of Ophthalmology or due to a shortage of ganciclovir.</p> <p>The Group accepted the restricted local need for Aciclovir Agepha 30mg/g eye ointment for the treatment herpes simplex keratitis.</p> <p><b>SBAR - Aciclovir Agepha 30mg/g eye ointment is routinely available in line with local guidance.</b></p> <p><b>Indication under review: the treatment of herpes simplex keratitis.</b></p> <p><b>Restriction:</b></p> <ul style="list-style-type: none"><li>• <b>first-line topical agent for children and adolescents</b></li><li>• <b>second-line topical agent for adults aged 18 years and older only on the advice of ophthalmology or when ganciclovir 0.15% is not available.</b></li></ul> <p><b>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.</b></p>	<p><b>FTeam</b></p>

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
7.	<b>OTHER BUSINESS</b>	
7.1.	<b>DECLARATIONS OF INTEREST 2019</b>	
	<p>The Chairman reminded members that annual declarations of interest must be completed for calendar year 2019.</p> <p>Ms Doney confirmed that the Formulary Team is currently clarifying the retention period for the records, both hard copy records and summary records. The Team maintains a summary of members' declarations in an excel spreadsheet, and the summary register will be presented at the March meeting.</p> <p>Ms Doney reminded members that NHS Grampian employees should also record their conflicts of interest on the NHS Grampian Corporate Register. A link to the Corporate Register will be emailed to members.</p>	<p>FTeam</p> <p>FTeam</p>
7.2.	<b>EMA SAFETY REVIEW OF PICATO®</b>	
	<p>The Chairman highlighted that the Marketing Authorisation Holder (MAH) for Picato® has decided to withdraw the marketing authorisation for this medicine. The European Medicines Agency (EMA) safety review is ongoing with the final outcome expected later this year.</p> <p>Ms Doney confirmed that use [of Picato®] in Primary Care is minimal, other treatment options are available on the dermatology patient pathway, and the medicine will be noted as non-formulary.</p>	<p>FTeam</p> <p>FTeam</p>
7.3.	<b>MELATONIN – UPDATE</b>	
	<p>The Chairman informed the Group that a licensed immediate-release 3mg melatonin tablet is now marketed in the UK.</p> <p>Ms Doney confirmed:</p> <ul style="list-style-type: none"><li>Pharma Nord has licensed an immediate-release 3mg tablet, Melatonin Pharma Nord 3mg film-coated tablets. It is the same as Bio-Melatonin 3mg immediate-release tablets.</li><li>Melatonin Pharma Nord 3mg film-coated tablets cost £15.95 for 30 tablets</li></ul> <p>Information will come to a future meeting.</p>	<p>FTeam</p> <p>FTeam</p>
7.4.	<b>CONSENSUS STATEMENT ON THE MANAGEMENT OF ADVANCED RENAL CELL CARCINOMA FROM SCOTTISH RENAL ONCOLOGY CONSULTANT GROUP</b>	
	<p>The Chairman highlighted the consensus statement on the management of advanced renal cell carcinoma from the Scottish Renal Oncology Consultant Group.</p> <p>The Group discussed the difficult situation with licensing and the lack of evidence to support potential sequencing of agents.</p> <p>The Group agreed that in the absence of evidence/SMC/HIS advice, and provided the Group has taken reasonable steps to gather the relevant information, following a specialist consensus view would be appropriate.</p>	
8.	<b>NEW PRODUCT REQUESTS</b>	
	<p>Items 8.1 to 8.3 were discussed under item 3, and items 8.4 and 8.5 were taken together.</p> <p><b>8.4. FG1SMC 1260/17 AMELUZ® GEL (BASAL CELL CARCINOMA)</b></p> <p><b>8.5. FG1SMC 811/12 AMELUZ® GEL (ACTINIC KERATOSIS)</b></p> <p>There were no declarations of interest recorded in relation to this product.</p>	

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	<p>The Group considered the requests for Ameluz<sup>®</sup>, as licensed, for basal cell carcinoma (BCC) and actinic keratosis (AK).</p> <p>The Group noted:</p> <ul style="list-style-type: none"><li>• Ameluz<sup>®</sup><ul style="list-style-type: none"><li>• would be an alternative to Metvix<sup>®</sup> (methyl-5-aminolevulinate 160mg/g) cream, which is already included on the formulary for the same indications</li><li>• only had one licensed indication [AK] when it was first marketed (~ 10 years ago), and it was marketed at a higher list price [£184.00 per 2g sachet]. The list price is now lower than Metvix<sup>®</sup> [£170.00 versus £171.50 ref DM&amp;D accessed 15/01/2020].</li><li>• is more efficacious than Metvix<sup>®</sup> for AK</li></ul></li><li>• both products are used in combination with photodynamic therapy, and use is restricted to 'specialist use only'</li><li>• Metvix<sup>®</sup> cream will no longer be preferred for AK and BCC, but will remain on the formulary for the treatment of squamous cell carcinoma in situ (Bowen's disease) when surgical excision is considered less appropriate</li></ul> <p>The Group accepted the restricted local need for Ameluz<sup>®</sup> as licensed in combination with photodynamic therapy for basal cell carcinoma (BCC) and actinic keratosis.</p> <p><b>SMC 1260/17 and SMC 811/12 - 5-aminolaevulinic acid (as hydrochloride) 78mg/g gel (Ameluz<sup>®</sup>) is routinely available in line with local guidance.</b></p> <p><b>Indications under review:</b></p> <ul style="list-style-type: none"><li>- for the treatment of superficial and/or nodular basal cell carcinoma (BCC) unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome in adults.</li><li>- for the treatment of actinic keratosis of mild to moderate severity on the face and scalp (Olsen grade 1 to 2) and of field cancerization in adults.</li></ul> <p><b>It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. Ameluz<sup>®</sup> should only be administered under the supervision of a physician, a nurse or other healthcare professional experienced in the use of photodynamic therapy.</b></p>	<p><b>FTeam</b></p>
<b>9.</b>	<p><b>SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – JANUARY 2020</b></p> <p>The Group noted the SMC provisional advice issued January 2020.</p> <p>If the negative SMC recommendations and non-submission statements are published next month, these medicines will not be included on the formulary for the indications in question.</p> <p><b>SMC 2225 - TEDUGLUTIDE 5MG VIAL OF POWDER AND SOLVENT FOR SOLUTION FOR INJECTION (REVESTIVE<sup>®</sup>)</b></p> <p>The Group noted the provisional advice for teduglutide for the treatment of adults with short bowel syndrome (SBS).</p> <p>It was confirmed that teduglutide is already included on the formulary for use in children and adolescents (1 to &lt; 17 years), and this SMC advice relates to use in adult patients.</p> <p>The Group agreed that a licence extension to include adults is an unusual situation; paediatric licence extensions are more commonplace. Generally, the Formulary Group does not request a full submission for paediatric licence extensions, and it was agreed that the same principle would apply to the adult licence extension for teduglutide.</p> <p>A summary will be prepared for the February meeting.</p>	<p><b>FTeam</b></p>

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	SMC 2249 - PLERIXAFOR 20MG/ML SOLUTION FOR INJECTION (MOZOBIL®)	
	It was confirmed that NHS Grampian does not undertake stem cell harvesting in children, paediatric patients are treated in a specialist centre in another Health Board. There is an expectation that the specialist centre would supply and administer plerixafor prior to the patients having the procedure.	
	The Group agreed that plerixafor should be recorded as non-formulary for this indication. A summary will be prepared for the February meeting.	FTeam

**10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS – JANUARY 2020**

The Group noted the SMC advice published January 2020

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

- SMC 2215 abiraterone acetate (Zytiga®) (submission expected)
- SMC 2229 brentuximab (Adcetris®)▼ (submission received)
- SMC 2226 fremanezumab (Ajovy®)▼ (submission expected)
- SMC 2223 ocrelizumab (Ocrevus®)▼ (submission received)

Local advice for these medicines and indications will be included in the January 2020 decisions as 'Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.'

**FG1SMC 2232 – DUPILUMAB (MODERATE-TO-SEVERE ATOPIC DERMATITIS IN ADOLESCENTS ≥12 TO <18 YEARS)**

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

The Group discussed the abbreviated SMC advice for the paediatric extension of dupilumab for the treatment of moderate-to-severe atopic dermatitis.

The Group noted:

- dupilumab:
  - is included on the formulary for adults for the same indication
  - is now also available as a 200mg injection, and the two strengths [200mg and 300mg] are flat priced
- the licence has been extended to include adolescents aged ≥12 to <18 years
- the Paediatric Service has no patients waiting for treatment but would like to have the licence extension recognised on the formulary to facilitate access to treatment should a local need arise in the future

The Group accepted the restricted local need for dupilumab for the treatment of moderate-to-severe atopic dermatitis in adolescents (≥12 to <18 years) who are candidates for systemic therapy, without the need for a full submission.

**SMC 2232 - Dupilumab 200mg and 300mg solution for injection in pre-filled syringe (Dupixent®)▼ is routinely available in line with national guidance (SMC 2232).**

**Indication under review: for the treatment of moderate-to-severe atopic dermatitis in adolescents 12 years and older who are candidates for systemic therapy..**

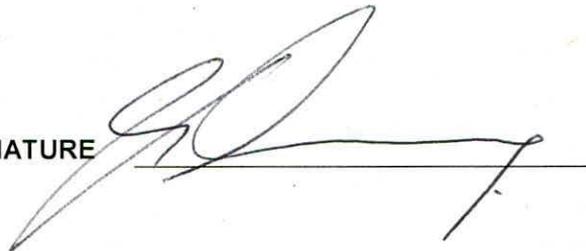
**Restriction: patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable.**

**SMC has previously accepted dupilumab for restricted use under the orphan medicine process for the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy (SMC 2011). This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.**

**PROTECTIVE MARKING: NONE**

ITEM	SUBJECT	ACTION
	<p>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 by healthcare professionals experienced in the diagnosis and treatment of conditions for which dupilumab is indicated.</p>	FTeam
11.	<p><b>GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM – JANUARY 2020</b> None.</p>	
12.	<p><b>DOCUMENTS FOR INFORMATION</b> Items 12.1 (Drug Safety Update December 2019), item 12.2 (AMT minute September 2019) and item 12.3 (Responsibility for Prescribing across Secondary and Primary Care Guideline) were noted.</p>	
13.	<p><b>AOCB - NONE</b></p>	
	<p><b>DATE OF NEXT MEETING</b> Tuesday 18 February 2020 starting at 14.30 in the Seminar Room, David Anderson Building.</p>	

**CHAIRMAN'S SIGNATURE**



**DATE**

**18 February 2020**