# NHS GRAMPIAN
## Minute of Formulary Group Meeting
## Tuesday 16 May 2023 at 14:30 via Microsoft Teams

| PRESENT | APOLOGIES | APPROVED |
|---|---|---|
| Miss R Anderson | Dr D Culligan | |
| Ms L Cameron | Mrs G McKerron | |
| Dr V Chieng | | |
| Ms A Davie | | |
| Ms F Doney (Vice-Chair) | | |
| Dr E Elias | | |
| Dr L Elliot (Chair) | | |
| Dr M Metcalfe (Vice-Chair) | | |
| Mr M Paterson | | |
| Mr R Sivewright | | |

**IN ATTENDANCE**
Mrs Emma Milne, Lead Pharmacist, Aberdeenshire

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WELCOME

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

Mrs Emma Milne, Lead Pharmacist Aberdeenshire, was introduced to the Group. Mrs Milne was attending the meeting as an observer with a plan to join the Group, as a Primary Care Pharmacy representative, from the June meeting to cover while Mrs Neave is off.

**1. APOLOGIES**

Apologies for absence were requested and noted.

**2. DRAFT MINUTE OF THE MEETING HELD 18 APRIL 2023**

The Group 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**

**3. PRESENTATION**

None.

**4. MATTERS ARISING**

**4.1. ACTION LOG**

The action log was noted.

No additional items were identified for discussion at the meeting.

**4.2. SMC 2478 OZANIMOD AND SMC 2510 UPADACITINIB (ULCERATIVE COLITIS)**

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

The requests to include ozanimod and upadacitinib on the formulary for the treatment of

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adults with moderately to severely active ulcerative colitis (UC) were discussed at the March meeting, but decision-making was deferred pending confirmation of the queries posed in the reviews.

Members reviewed the replies to the queries and supported inclusion of upadacitinib as an alternative Janus kinase (JAK) inhibitor [to tofacitinib] for the treatment of UC. **FTEAM**

Members considered the Ozanimod Prescribers Checklist and discussed the Service's replies to the queries for ozanimod. It was noted that:

- to allow introduction of ozanimod, new and additional pressures are expected on other services, e.g., laboratory and blood pressure monitoring; the need for consultation with cardiology and a baseline electrocardiogram (ECG); people with diabetes, uveitis, or retinal disease require a pre-treatment ophthalmologic examination.
  Pressure on nursing staff - at initiation, some patients require hourly heart rate and blood pressure monitoring for at least the first 6 hours. Some patients also require a repeat ECG 6 hours after the first dose.
- the arrangements for pre- and post-treatment assessment, and ongoing monitoring were not finalised [26 April]
- if ozanimod was being considered for a patient with pre-existing cardiac conditions there would be discussion at the inflammatory bowel disease (IBD) multi-disciplinary team meeting and liaison with Cardiologist(s)
- there were possible discrepancies in the replies, in terms of the plans for ongoing monitoring, with mention of transfer of blood pressure monitoring to Primary Care for patients who had no pre-existing cardiac conditions, but also Secondary Care Hubs and IBD Clinic were mentioned as sites for regular checks

The Nursing representative was unable to attend the meeting but submitted comments by email highlighting that if there is a requirement to observe patients for 6 hours in clinics within ARI, then the nursing team do not have capacity to support this, and recommended that discussions are held with senior nursing colleagues prior to implementation.

General Practice representatives highlighted that Primary Care does not have the capacity to take on additional blood pressure monitoring. If a patient has pre-existing hypertension then standard blood pressure monitoring would be undertaken, but no additional monitoring could be transferred to Primary Care.

Whilst accepting there is a need for an additional treatment option with a different mode of action, members agreed that sufficient nursing capacity was required to allow the safe introduction of ozanimod.

In view of the concerns regarding nursing capacity and procedures for pre-, post-initiation checks and ongoing monitoring, the Group gave a conditional acceptance for ozanimod for UC. Senior nursing colleagues should be included in discussions to ensure that there is sufficient nursing capacity to allow the required pre- and post-initiation monitoring. Additionally, any new or additional blood pressure monitoring would remain the responsibility of the managed service, e.g., via the Secondary Care hubs/Homecare arrangement/IBD Clinics.

**SMC 2478 - Ozanimod 0.23mg, 0.46mg, 0.92mg hard capsules (Zeposia®) ▼ is routinely available in line with national guidance (SMC 2478).**
**Indication under review: for the treatment of adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.**
**In a randomised, double-blind, phase III study in patients with moderately to severely active UC, clinical remission was achieved by a significantly greater proportion of patients who received ozanimod compared with placebo after induction and maintenance treatment.**

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| | **This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the economic 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 under the supervision of a physician experienced in the management of ulcerative colitis.** | **FTEAM** |

The Group accepted the restricted local need for upadacitinib as an alternative JAK inhibitor for the treatment of adults with moderately to severely active UC, as outlined in SMC 2510.

**SMC 2510 - Upadacitinib 15mg, 30mg, 45mg prolonged-release tablets (Rinvoq®) ▼ is routinely available in line with national guidance (SMC 2510).**
**Indication under review: for the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.**
**Upadacitinib offers an additional treatment choice in the therapeutic class of Janus kinase inhibitors.**
**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 with upadacitinib should be initiated and supervised by physicians experienced in the diagnosis and treatment of conditions for which upadacitinib is indicated.** **FTEAM**

The Group supported the request to reclassify tofacitinib, for moderately to severely active ulcerative colitis, as non-formulary - Not routinely available as there is a local preference for alternative medicines.

**SMC 2122 - Tofacitinib 5mg, 10mg film-coated tablets (Xeljanz®) is not routinely available as there is a local preference for alternative medicines.**
**Indication under review: for the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.**
**Not routinely available as there is a local preference for alternative medicines.** **FTEAM**

People currently established on tofacitinib for UC may continue to receive treatment until they and their clinician consider it appropriate to stop.

## 5. FORMULARY GROUP DECISIONS APRIL 2023 - PUBLISHED 27/04/2023

Members ratified the decisions of the April 2023 meeting as published.

## 6. NETFORMULARY/FORMULARY REVIEW

### 6.1. SBAR LUFORBEC®

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

The Group reviewed the information from the Respiratory Managed Clinical Network (MCN) highlighting a change to its preferred combination inhaled corticosteroid (ICS) plus long-acting beta2 agonist (LABA) inhaler choices.

The Group noted that:
- a generic competitor to Fostair® pMDI is available
- the MCN wishes to replace Fostair® pressurised metred-dose inhaler (pMDI) with

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Luforbec® pMDI, and remove Flutiform® pMDI from the preferred products included in the latest update of the NHS Grampian Respiratory MCN asthma prescribing guidance

- generic medicines are considered outwith remit for SMC so Luforbec® will not be assessed nationally
- the dosing and licensing of Luforbec® is the same as Fostair®, but at list price costs £8.80 less per inhaler
- the Respiratory MCN:
  - has assessed placebo devices and supports the introduction of Luforbec® as a suitable generic substitute for Fostair® pMDI and the preferred ICS/LABA pMDI for the local adult asthma prescribing guidance
  - notes that the propellant in Flutiform® pMDI has a more powerful greenhouse effect than other inhalers that contain similar medicines
  - notes that Flutiform® and Fostair® pMDI will no longer be included in the adult prescribing guidance, but will remain on formulary for patients established on treatment until their treatment is reviewed

The Group supported the changes proposed by the Respiratory MCN, noting that Fostair® and Flutiform® pMDIs will no longer be promoted as preferred products. **FTEAM**

**Luforbec® 100micrograms/6micrograms, 200micrograms/6micrograms pressurised inhalation solution (beclometasone dipropionate/ formoterol fumarate dihydrate) is routinely available in line with local guidance.**
**Indication under review: for the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate:**

- **patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled rapid-acting beta2-agonist or**
- **patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists**

**Restriction: use is subject to inclusion in the Respiratory MCN framework for inhaled medicines.**
**It was classified 1a – available for general use and 8e – treatment may be initiated in either hospital or community.** **FTEAM**

Members authorised early publication of the decisions to allow sharing of the information regarding the changes to preferred choices at the MCN Respiratory conference. **FTEAM**

## 7. OTHER BUSINESS

### 7.1. NCMAG QUARTERLY UPDATE

Members noted the content of the April 2023 National Cancer Medicines Advisory Group (NCMAG) quarterly update.

### 7.2. NHS GRAMPIAN FORMULARY GROUP NCMAG REPORTING

The Formulary Team proposed a report format and publication timelines for formulary decisions for National Cancer Medicines Advisory Group (NCMAG) advice. The report mirrors the format and timescales required by Scottish Government for local formulary decisions for SMC published advice.

The Group ratified the format and publication timelines proposed, and authorised publication of the report [by the Formulary Team]. **FTEAM**

### 7.3. CANCER MEDICINES OUTCOMES PROGRAMME (CMOP)

Members noted the content of the Cancer Medicines Outcomes Programme (CMOP) progress report.

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**8. NEW PRODUCT REQUESTS**

**8.1. SMC 2451 - PEGCETACOPLAN (PAROXYSMAL NOCTURNAL HAEMOGLOBINURIA (PNH))**

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

The Group considered the request for pegcetacoplan for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least 3 months.

The Group noted that:

- pegcetacoplan:
  - [for this indication] meets the SMC orphan criteria, and was accepted for use in NHS Scotland following a full submission reviewed by the SMC executive
  - is a pegylated cyclic peptide inhibitor of complement C3 which acts to exert a broad inhibition of the complement cascade thereby controlling the mechanisms leading to extravascular and intravascular haemolysis
  - is administered twice weekly, or increased to every third day, as a 1,080mg subcutaneous infusion. Subcutaneous infusion allows self-administration.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of pegcetacoplan
- in Scotland, patients with PNH are managed by the National PNH Service in consultation with their local haematologist and are referred to the national service via an outreach clinic in Monklands Hospital
- current treatments for PNH include ravulizumab (SMC 2305) and eculizumab. Eculizumab is not recommended for use in NHS Scotland, SMC 1130/16, but patients' access treatment through individual requests/PACS1 applications.
- eculizumab and ravulizumab only act to control intravascular haemolysis and do not control extravascular haemolysis
- patient numbers are expected to be very small, but medicine costs are very high
- costs are already in the system with cost offset available from displacement of C5 inhibitor(s)

The Group accepted the restricted local need for pegcetacoplan, as outlined in SMC 2451.

**SMC 2451 - Pegcetacoplan 1,080mg solution for infusion (Aspaveli®) ▼ is routinely available in line with national guidance (SMC 2451).**
**Indication under review: in the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least 3 months.**
**Restriction: under the advice of the national PNH service.**
**In an open-label, randomised, phase III study in patients anaemic after at least 3 months treatment with a C5 inhibitor, there was a significantly greater improvement in haemoglobin levels after 16 weeks of treatment with pegcetacoplan compared with continued C5 inhibitor treatment.**
**This advice applies only in the context of approved NHS Scotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.**
**It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Therapy should be initiated under the supervision of a healthcare professional experienced in the management of patients with haematological disorders.** FTEAM

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**8.2. SMC 2494 - ABEMACICLIB (HR-POSITIVE, HER2-NEGATIVE, NODE POSITIVE EARLY BREAST CANCER)**

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

The Group considered the request for abemaciclib in combination with endocrine therapy for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence. In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.

The Group noted that:

- abemaciclib:
  - is taken orally at a recommended dose of 150mg twice daily when used in combination with endocrine therapy
  - [for this indication] is taken continuously for two years, or until disease recurrence or unacceptable toxicity occurs
  - [for this indication] is indicated for patients at high risk of recurrence, and the NICE TA810 definition of 'high risk' will be used locally
  - is already included on formulary for advanced/metastatic breast cancer, and if used in early breast cancer patients will not be re-treated in the advanced/metastatic setting
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of abemaciclib
- the aim of adjuvant therapy in patients who have been deemed cancer-free is to improve the cure rate. At the latest analysis, overall survival data were immature and no survival benefit was observed; longer-term data are required to confirm a treatment effect on later recurrences and survival. The company has committed to providing 5-year follow-up data of monarchE (ref SMC 2494).
- the SMC highlighted that presently patients receiving adjuvant endocrine therapy are managed in general practice and the addition of abemaciclib could have substantial service implications as patients would be treated and monitored by oncologists. However, the Service has confirmed there is capacity for their estimated patient numbers.
- this is a new cost to the system, and costs will be cumulative as treatment is taken for up to two years

Members discussed reservations about approval because of the immaturity of overall survival data, and although a time-limited regimen, the cost of treatment is high.

The Group accepted the restricted local need for abemaciclib in combination with endocrine therapy for the adjuvant treatment of adults with HR-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence, as outlined in SMC 2494.

**SMC 2494 - Abemaciclib 50mg, 100mg, 150mg film-coated tablets (Verzenios®) ▼ is routinely available in line with national guidance (SMC 2494).**
**Indication under review: in combination with endocrine therapy for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence. In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.**
**In an open-label, randomised, phase III study, the addition of abemaciclib to adjuvant endocrine therapy improved invasive disease-free survival (IDFS) compared with endocrine therapy alone in patients with HR-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence. The cohort**

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**of study patients with either at least four positive axillary lymph nodes or one to three positive axillary lymph nodes plus either grade 3 disease and/or tumour size ≥5cm supported the evidence for patients of high risk of recurrence in clinical practice.**
**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. Therapy should be initiated and supervised by physicians experienced in the use of anti-cancer therapies.** **FTEAM**

### 8.3. SMC 2482 - ASCIMINIB (PH+ CHRONIC MYELOID LEUKAEMIA IN CHRONIC PHASE)

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

The Group considered the request to include asciminib on the formulary for the treatment of adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), and without a known T315I mutation.

The Group noted that:

- asciminib:
  - [for this indication] meets SMC orphan criteria and was accepted for use in NHS Scotland following a full submission assessed under the orphan equivalent medicine process, the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios
  - is an alternative TKI for the treatment of CML, limited to chronic phase CML
  - has a novel mechanism of action, which may offer the potential to maintain activity against ABL1 kinase domain mutations that cause resistance to other TKIs
  - is taken orally either as 80mg once daily or as 40mg twice daily
- the requestor has confirmed that asciminib will be used third line. Currently all formulary TKIs (imatinib, dasatinib, nilotinib, bosutinib, ponatinib) could be used in this setting if not used previously, although for most patients the competitor drugs will be bosutinib and ponatinib.
- bosutinib and ponatinib use will decrease but not stop completely
- patient numbers are expected to be very small, and cost offset is available from displacement of alternative TKIs, although costs will be cumulative as treatment is likely to be taken for several years

The Haematology pharmacist confirmed that sometimes bosutinib is not well tolerated and it is hoped that asciminib would be better tolerated, which would be a significant benefit to patients. Also, there is a school of thought that some people may not cycle through all of the TKIs, if you have a suitable molecular response/depth of response then after several years treatment there may be the potential to stop treatment.

The Group accepted the restricted local need for asciminib for the treatment of adults with Ph+ CML-CP, as outlined in SMC 2482.

**SMC 2482 - Asciminib 20mg, 40mg film-coated tablets (Scemblix®) ▼ is routinely available in line with national guidance (SMC 2482).**
**Indication under review: for the treatment of adults with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), and without a known T315I mutation.**
**In an open-label, phase III study, asciminib was associated with significantly higher major molecular response rates than another TKI in patients with Ph+ CML-CP who**

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| | **had received at least two previous TKIs and did not have a T315I mutation. 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. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated by a physician knowledgeable in the diagnosis and treatment of patients with chronic myeloid leukaemia.** | **FTEAM** |

Items 8.4 to 8.6 were taken together.

**8.4. FG1SMC 2532 - UPADACITINIB (NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA)) AND**

**8.5. FG1SMC 2463 - TOFACITINIB (ACTIVE ANKYLOSING SPONDYLITIS) AND**

**8.6. FG1SMC 2480 - UPADACITINIB (ACTIVE ANKYLOSING SPONDYLITIS)**

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

The Group considered the requests for upadacitinib and tofacitinib for adults with ankylosing spondylitis (AS), and upadacitinib for adults with non-radiographic axial spondyloarthritis.

The Group noted that:

- upadacitinib and tofacitinib are JAK inhibitors
- the recommended dose of upadacitinib, for AS and non-radiographic axial spondyloarthritis, is 15mg orally once daily
- [for these indications] tofacitinib is only licensed for AS and the recommended dose is 5mg orally twice daily or 11mg prolonged-release once daily
- the SMC review for tofacitinib only included tofacitinib 5mg tablets, but the Service wishes to include the 11mg prolonged-release tablet in its request
- tofacitinib 11mg prolonged-release tablet administered once-daily is equivalent to 5mg film-coated tablet administered twice daily. The daily cost is the same regardless of the formulation used.
- JAK inhibitors offer a different mode of action to the alternative treatment options, they are oral tablets rather than injections, and do not require refrigeration
- for JAK inhibitors when used to treat chronic inflammatory disorders, the Medicines and Healthcare products Regulatory Agency (MHRA) Drug Safety Update recently issued new risk minimisation measures to reduce the risks of major cardiovascular events, malignancy, venous thromboembolism, serious infections and increased mortality
- the Rheumatology Service has recently reviewed their patients receiving JAK inhibitors and overall have found good safety profiles
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of upadacitinib and tofacitinib
- cost offset will be available from the displacement of alternative treatment options, costs will be cumulative as these are potentially long-term treatment options
- fewer patients are expected to be treated with tofacitinib (across all indications)
- treatment will be supplied using a Homecare arrangement
- the Service plans to use upadacitinib after patients have received treatment with tumour necrosis factor-alpha inhibitor(s) and secukinumab. Tofacitinib would only be used after upadacitinib for patients with AS. [The treatment pathway is the same for AS and non-radiographic axial spondyloarthritis].

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For adults with AS, the Group accepted the restricted local need for upadacitinib and tofacitinib, including the 11mg prolonged-release tablet, as outlined in SMC 2532 and SMC 2463.
The Group also accepted the restricted local need for upadacitinib for non-radiographic axial spondyloarthritis, as outlined in SMC 2480.

**SMC 2532 - Upadacitinib 15mg prolonged-release tablets (Rinvoq®) ▼ is routinely available in line with national guidance (SMC 2532).**
**Indication under review: for the treatment of active non-radiographic axial spondyloarthritis in adults with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).**
**Upadacitinib offers an additional treatment choice in the therapeutic class of immunosuppressants.**
**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 with upadacitinib should be initiated and supervised by physicians experienced in the diagnosis and treatment of conditions for which upadacitinib is indicated.** FTEAM

**SMC 2463 - Tofacitinib 5mg film-coated tablets, 11mg prolonged-release tablets (Xeljanz®) is routinely available in line with national guidance (SMC 2463).**
**Indication under review: for the treatment of adults with active ankylosing spondylitis (AS) who have responded inadequately to conventional therapy.**
**In a phase III and phase II study, tofacitinib compared with placebo, significantly improved symptoms of AS in adults with active disease inadequately controlled with nonsteroidal anti-inflammatory drugs.**
**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 specialist physicians experienced in the diagnosis and treatment of conditions for which tofacitinib is indicated.** FTEAM

**SMC 2480 - Upadacitinib 15mg prolonged-release tablets (Rinvoq®) ▼ is routinely available in line with national guidance (SMC 2480).**
**Indication under review: for the treatment of active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy.**
**In a phase III and a phase II/III study, upadacitinib when compared with placebo, significantly improved symptoms of AS in adults with active disease that was inadequately controlled with non-steroidal anti-inflammatory drugs (NSAIDs).**
**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 with upadacitinib should be initiated and supervised by physicians experienced in the diagnosis and treatment of conditions for which upadacitinib is indicated.** FTEAM

The Rheumatology Service also requested that tofacitinib 11mg prolonged-release tablet is considered for formulary inclusion for all of its other rheumatological indications.

The Group noted that:
- tofacitinib 11mg prolonged release tablet is currently only licensed for the

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management of rheumatological conditions in adults (rheumatoid arthritis, psoriatic arthritis and AS)
- tofacitinib 5mg tablets is already included on formulary for severe active rheumatoid arthritis and psoriatic arthritis in line with SMC 1298/18 and SMC 2116
- steady-state area under the curve (AUC) and peak concentrations (Cmax) of tofacitinib 11mg prolonged-release tablet administered once daily are equivalent to tofacitinib 5mg film-coated tablet administered twice daily
- formulary inclusion of tofacitinib 11mg prolonged-release tablets would be cost neutral but allow once-daily dosing as with the other JAK inhibitors

The Group accepted the restricted local need for tofacitinib 11mg prolonged-release tablets in line with the current formulary acceptance for severe active rheumatoid arthritis and active psoriatic arthritis, without the need for full submissions.

**Tofacitinib 11mg prolonged-release tablets (Xeljanz®) is routinely available in line with local guidance.**
**Indication under review: for the treatment of adults with:**
- **severe active rheumatoid arthritis in line with SMC 1298/18**
- **active psoriatic arthritis in line with SMC 2116**

**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 tofacitinib is indicated.** **FTEAM**

Items 8.7 and 8.8 were taken together.

**8.7. FG1SMC 2495 - UPADACITINIB (MODERATE ACTIVE RHEUMATOID ARTHRITIS) AND**

**8.8. FG1SMC 2475 - FILGOTINIB (MODERATE ACTIVE RHEUMATOID ARTHRITIS)**

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

The Group considered the requests for the JAK inhibitors filgotinib and upadacitinib for the treatment of adults with moderate active rheumatoid arthritis (a disease activity score [DAS28] of 3.2 to 5.1) who have responded inadequately to, or who are intolerant to intensive therapy with two or more conventional disease-modifying anti-rheumatic drugs (DMARDs).

The Group noted that:
- moderate disease is defined as a DAS28 of 3.2 to 5.1
- filgotinib and upadacitinib are included on the formulary for severe RA [i.e., DAS28 >5.1]
- since release of these SMC advice documents the tumour necrosis factor-alpha inhibitors were included on formulary for moderate RA in line with NICE advice
- JAK inhibitors offer a different mode of action to the alternative treatment options, they are oral tablets rather than injections, and do not require refrigeration
- the new risk minimisation measures for JAK inhibitors apply (MHRA DSU)
- cost offset will be available from the displacement of alternative treatment options, and costs will be cumulative as these are potentially long-term treatment options

The Group accepted the restricted local need for filgotinib and upadacitinib for the treatment of adults with moderate active rheumatoid arthritis, as outlined in SMC 2495 and SMC 2475.

**SMC 2495 - Upadacitinib 15mg prolonged-release tablets (Rinvoq®) ▼ is routinely available in line with national guidance (SMC 2495).**
**Indication under review: for the treatment of adults with moderate active**

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| | **rheumatoid arthritis (a disease activity score [DAS28] of 3.2 to 5.1) who have responded inadequately to, or who are intolerant to intensive therapy with 2 or more conventional disease-modifying anti-rheumatic drugs (DMARDs).<br>Upadacitinib may be used as monotherapy or in combination with methotrexate.<br>In a phase III randomised, placebo-controlled and active comparator study in patients who had an inadequate response to methotrexate, upadacitinib significantly improved the signs and symptoms of RA compared with placebo.<br>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.<br>SMC has issued separate advice for upadacitinib in patients with severe disease (DAS28 greater than 5.1).<br>It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment with upadacitinib should be initiated and supervised by physicians experienced in the diagnosis and treatment of conditions for which upadacitinib is indicated.** | **FTEAM** |
| | **SMC 2475 - Filgotinib 100mg, 200mg film-coated tablets (Jyseleca®) ▼ is routinely available in line with local guidance.<br>Indication under review: for the treatment of adults with moderate active rheumatoid arthritis (a disease activity score [DAS28] of 3.2 to 5.1) who have responded inadequately to, or who are intolerant to intensive therapy with 2 or more conventional disease-modifying anti-rheumatic drugs (DMARDs).<br>Filgotinib may be used as monotherapy or in combination with methotrexate.<br>In a post hoc subgroup analysis from a phase III study, filgotinib compared with placebo (in combination with methotrexate) improved the signs and symptoms of moderate rheumatoid arthritis (DAS28[CRP] >3.2 to ≤5.1) in patients with an inadequate response to conventional DMARDs.<br>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.<br>SMC has issued separate advice for filgotinib in patients with severe disease (DAS28 greater than 5.1).<br>It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment with filgotinib should be initiated by a physician experienced in the treatment of rheumatoid arthritis.** | **FTEAM** |

## 9. PROVISIONAL ADVICE ISSUED MAY 2023

### 9.1. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE MAY 2023

The Group noted the SMC provisional advice issued May 2023.

## 10. PUBLISHED ADVICE - MAY 2023

### 10.1. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE MAY 2023

The Group noted the SMC advice published May 2023.

Following publication of the negative SMC recommendations for icosapent ethyl (Vazkepa®)▼ SMC 2531, rimegepant (Vydura®)▼ SMC 2567 and tafasitamab (Minjuvi®) ▼ SMC 2522, 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 2523 - empagliflozin (Jardiance®) (submission expected)
- SMC 2521 - rimegepant (Vydura®)▼ (submission expected)

| ITEM | SUBJECT | ACTION |
|---|---|---|
| | Local advice for these medicines and indications will be included in the May 2023 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. | FTEAM |

**10.2. NATIONAL CANCER MEDICINES ADVISORY GROUP (NCMAG) ADVICE APRIL 2023**

The Group noted the NCMAG advice published April 2023.

Following publication of the not supported recommendation for vinorelbine tartrate (Navelbine®) NCMAG 108, this medicine will not be included on the Grampian Joint Formulary for the indication in question. **FTEAM**

**11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM - MAY 2023**

None.

**12. DOCUMENTS FOR INFORMATION**

Items 12.1 (Drug Safety Update April 2023) and 12.2 (Antimicrobial Management Team minute March 2023) were noted.

**13. AOCB**

None.

**DATE OF NEXT MEETING**

Tuesday 20 June 2023 starting at 14.30 via Microsoft Teams

**CHAIR'S SIGNATURE**  **DATE 20 JUNE 2023**