

NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 15 June 2021 at 14:30 via Microsoft Teams

PRESENT

Ms F Doney
Dr L Elliot
Dr J Fitton
Ms M Galvin
Professor J McLay (Chairman)
Dr M Metcalfe
Mrs L Montgomery
Mrs K Neave
Mrs S O'Beirne
Mr M Paterson
Mr R Sivewright

APOLOGIES

Ms A Davie

APPROVED

IN ATTENDANCE

Ms Christine Hay, Formulary and Medicines Management Pharmacist

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

1. APOLOGIES

Apologies for absence were requested and noted.

2. DRAFT MINUTE OF THE MEETING HELD 18 MAY 2021

The Group accepted the draft note of the May meeting subject to minor typographical changes.

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

FD

Ms Doney reported that an error was found in the published April decisions document [emtricitabine was omitted from the components included in Stribild®]. The document has been corrected and republished.

3. PRESENTATION - NONE

4. MATTERS ARISING

4.1. ACTION LOG

The action log was noted.

No additional items were identified that should have been included on the agenda.

4.2. BORON IN EYE DROPS (OTHER THAN CHLORAMPHENICOL)

At the May meeting the Grampian Medicines Information Centre was asked to check if there were eye drops licensed for use in children under 2 years of age [other than chloramphenicol] that included boric acid as an excipient.

Mrs O'Beirne reminded members that the European Medicines Agency (EMA) has recommended that chloramphenicol 0.5% eye drops containing boric acid as an excipient are contraindicated for use in children under 2 years of age. This is due to an associated future risk of impaired fertility. The Medicines and Healthcare products Regulatory Agency (MHRA) is considering the available evidence in collaboration with specialists and plans to issue a statement in due course.

Mrs O'Beirne confirmed that only the chloramphenicol eye drops Summary of Product

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ITEM	SUBJECT	ACTION
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Characteristics (SmPCs) are currently updated to include the contraindication.

Mrs O'Beirne presented the results of a search of the electronic medicines compendium (emc) and confirmed that:

- eye drops containing boron/boric acid were excluded if they were not licensed for use in children under 2 years of age
- there are some glaucoma, dry eye, anti-infective and diagnostic preparations that contain boron/boric acid as an excipient
- in most cases, alternative formulations or preparations are available which do not contain boron/boric acid

The Group agreed that in most cases children requiring regular eye drops will be under the care of the Ophthalmologists, and that it would be helpful to include a generic statement to avoid use in under 2 years on the relevant formulary preparations.

Mrs O'Beirne and Ms Doney will liaise with colleagues in Ophthalmology to consider the inclusion of a general advice notice on the relevant section(s) of the formulary.

SO/FD

4.3. CARIPRAZINE – INTERACTION WARNING ON EMIS (UPDATE)

Mrs Neave reported that feedback from the local IT facilitators is that EMIS takes its interactions from the British National Formulary (BNF) database.

Ms Neave will contact EMIS directly for a more robust reply, meantime the difference in tone between 'avoid' and 'contraindicated' remains.

The item was closed pending update from EMIS.

5. FORMULARY GROUP DECISIONS MAY 2021 - PUBLISHED 31/05/2021

Members ratified the decisions of the May 2021 meeting as published.

6. NETFORMULARY/FORMULARY REVIEW

6.1. PAEDIATRIC LICENCE EXTENSIONS - EMTRICITABINE/TENOFOVIR (PREP)

Dr Fitton declared a personal, non-specific interest in Gilead Sciences Ltd and took part in decision-making.

The Group considered the proposed recommendation for the licence extension of the fixed-dose combination tablet emtricitabine (200mg) and tenofovir disoproxil fumarate (245mg), to include pre-exposure prophylaxis (PrEP) of HIV (human immunodeficiency virus) in adolescents aged 12 to less than 18 years at high risk.

The Group noted that:

- the nucleoside reverse transcriptase inhibitors emtricitabine and tenofovir disoproxil are available in a fixed-dose combination tablet [200mg/245mg]. The combination is included on the formulary for the treatment of HIV-1 infected adults and adolescents.
- the originator product Truvada® was the first medicine licensed for PrEP. April 2017 it was included on the formulary in line with SMC advice [SMC 1225/17] - for use in combination with safer sex practices for PrEP to reduce the risk of sexually acquired HIV-1 infection in adults at high risk.
- unlike medicines prescribed for HIV, prescribing of PrEP is limited to Sexual Health NHS Grampian
- Sexual Health NHS Grampian is requesting the use of PrEP in line with NHS Scotland PrEP eligibility criteria
- the age criterion in the national protocol is 16 years and over and Sexual Health NHS Grampian do not wish to extend formulary guidance to include patients under 16 years
- a request from an adolescent under 16 years would be reviewed on a case-by-case basis, following a child protection assessment as per Fraser guidelines and as per

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<p>British HIV Association (BHIVA) guidelines for under 16 years of age</p> <ul style="list-style-type: none">• previously use in adolescents would have been noted as off-label and the licence extension means that this is no longer required• patient numbers are expected to be very small, and approval will bring local guidance in line with the NHS Scotland PrEP eligibility criteria <p>The Group recognised the licence extension to include use in adolescents, but as requested by Sexual Health NHS Grampian, limited formulary acceptance to adults and adolescents from 16 years of age i.e., in line with the existing national guidance.</p> <p>Emtricitabine/tenofovir 200mg/245mg film-coated tablets is routinely available in line with national guidance. Indication under review: in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adolescents (16 to <18 years) at high risk. 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 experienced in the management of HIV infection - prescribing and supply restricted to the Sexual Health Service.</p> <p>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.</p>	
	<p>6.2. FULVESTRANT (FASLODEX®)</p> <p>Dr Fitton and Mr Paterson declared personal, non-specific interests in AstraZeneca UK Limited and took part in decision-making.</p> <p>Ms Hay confirmed that Faslodex® has now come off patent, and the formulary will be updated appropriately.</p> <p>There may be some cost implications related to the cost of the different generic preparations, however this is being considered elsewhere.</p>	<p>FTEAM</p> <p>FTEAM</p>
7.	<p>OTHER BUSINESS</p> <p>7.1. CMO REPORTING FOR FINANCIAL YEAR 2020/21</p> <p>The Chairman highlighted the new presentation of the CMO report. .</p> <p>He confirmed that for the financial year 2020/21 the Formulary Group audit standard (90%) was exceeded for the following criteria:</p> <ol style="list-style-type: none">1) Local decision on SMC accepted medicine reached within 90 days2) FG decision published within 14 days of the decision being reached <p>7.2. PHARMACY FIRST</p> <p>Ms Doney summarised the feedback received on the proposed Pharmacy First list and review process. Members reviewed and agreed the comments to be submitted.</p> <p>Ms Doney will finalise the Group's recommendations for submission by the 30 June deadline.</p>	
8.	<p>NEW PRODUCT REQUESTS</p> <p>Items 8.1 and 8.2 were taken together.</p> <p>8.1. FG1SMC 2302 - DARATUMUMAB SOLUTION FOR INFUSION AND</p> <p>8.2. FG1 SMC 2326 - DARATUMUMAB SOLUTION FOR INJECTION (NEWLY DIAGNOSED MULTIPLE MYELOMA)</p>	<p>FD</p>

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<p>There were no declarations of interest recorded in relation to this product.</p> <p>The Group reviewed the requests for daratumumab, as the intravenous and subcutaneous formulations, for use in combination with bortezomib, thalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.</p> <p>The Group noted that:</p> <ul style="list-style-type: none">• daratumumab:<ul style="list-style-type: none">▪ is included on the formulary for multiple myeloma, but used further down the pathway▪ [for this indication] meets SMC orphan criteria, and was accepted for use in NHS Scotland following the output from the PACE process, and application of SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios▪ [for this indication] is given weekly for the first eight doses then two-weekly for eight doses; 16 doses in total▪ should be administered by a healthcare professional, and the first dose should be administered in an environment where resuscitation facilities are available• the service has experience using daratumumab intravenous and subcutaneous formulations• most patients will receive subcutaneous daratumumab• patient numbers are expected to be small• the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of daratumumab• a new clinical trial, RADAR UK Myeloma XV trial, is opening later this year for this cohort of patients and eligible patients will be recruited to the trial <p>The Group accepted the restricted local need for daratumumab intravenous and subcutaneous formulations as outlined in SMC 2302 and SMC 2326.</p> <p>SMC 2302 - Daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®) ▼ is routinely available in line with national guidance (SMC 2302). Indication under review: in combination with bortezomib, thalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. The addition of daratumumab to bortezomib, thalidomide and dexamethasone was associated with significant improvement in stringent complete response rates in patients with newly diagnosed multiple myeloma who were eligible for autologous stem cell transplant. This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering 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. Daratumumab should be administered by a healthcare professional in an environment where resuscitation facilities are available.</p>	
	<p>SMC 2326 - Daratumumab 1,800mg solution for subcutaneous injection (Darzalex®) ▼ is routinely available in line with national guidance (SMC 2326). Indication under review: in combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. Following a submission under the orphan medicine process, SMC has previously</p>	<p>FTEAM</p>

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ITEM	SUBJECT	ACTION
	<p>accepted daratumumab concentrate for solution for infusion in combination with bortezomib, thalidomide and dexamethasone is indicated for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (SMC 2302).</p> <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.</p> <p>It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Daratumumab subcutaneous formulation is not intended for intravenous administration and should be given by subcutaneous injection only, using the doses specified.</p> <p>Daratumumab should be administered by a healthcare professional, and the first dose should be administered in an environment where resuscitation facilities are available.</p>	FTEAM

8.3. FG1SMC 1330/18 - MIDOSTAURIN (NEWLY DIAGNOSED ACUTE MYELOID LEUKAEMIA)

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

The Group reviewed the request for midostaurin for the treatment of adults with newly diagnosed acute myeloid leukaemia (AML) who are FLT3 mutation-positive, as outlined in SMC 1330/18.

The Group noted that:

- June 2018, following a full submission assessed under the old ultra-orphan and end of life medicine process, midostaurin was accepted for use within NHS Scotland in combination with standard daunorubicin and cytarabine induction and high-dose cytarabine consolidation chemotherapy, and for patients in complete response followed by midostaurin single agent maintenance therapy, for adults with newly diagnosed AML who are FLT3 mutation-positive
- midostaurin:
 - is an oral agent given in combination with induction and consolidation chemotherapy, or as monotherapy in the maintenance phase
 - is taken at a dose of 50mg twice daily; dosed on days 8 to 21 of induction and consolidation chemotherapy cycles, and for patients in complete response it is taken every day as single agent maintenance therapy until relapse for up to 12 cycles of 28 days each
 - was accepted for use in NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers
- patient numbers are expected to be small, and costs are already in the system
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of midostaurin

The Group accepted the restricted local need for midostaurin for the treatment of adults with newly diagnosed AML who are FLT3 mutation-positive, as outlined in SMC 1330/18.

SMC 1330/18 - Midostaurin 25mg soft capsules (Rydapt®) ▼ is routinely available in line with national guidance (SMC 1330/18).

Indication under review: in combination with standard daunorubicin and cytarabine induction and high-dose cytarabine consolidation chemotherapy, and for patients in complete response followed by midostaurin single agent maintenance therapy, for adult patients with newly diagnosed acute myeloid leukaemia (AML) who are FMS-like tyrosine kinase 3 (FLT3) mutation-positive.

In a randomised, double-blind, phase III study of adults (aged <60 years) with FLT3 mutation-positive AML, the addition of midostaurin to standard intensive chemotherapy regimen resulted in improved overall survival when compared with addition of placebo.

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	<p>The advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of midostaurin and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.</p> <p>This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.</p> <p>It was classified 1b - available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment with midostaurin should be initiated by a physician experienced in the use of anti-cancer therapies. Before taking midostaurin, AML patients must have confirmation of FLT3 mutation (internal tandem duplication [ITD] or tyrosine kinase domain [TKD]) using a validated test.</p>	FTEAM
8.4. FG1SMC 2308 - SECUKINUMAB (NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS)	<p>There were no declarations of interest recorded in relation to this product.</p> <p>The Group reviewed the request for secukinumab for the treatment of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs).</p> <p>The Group noted that:</p> <ul style="list-style-type: none">• secukinumab<ul style="list-style-type: none">▪ is already included on the formulary for rheumatological conditions; ankylosing spondylitis (radiographic axial spondyloarthritis) and psoriatic arthritis▪ is given as a weekly injection [150mg subcutaneous] for the first five doses, followed by 150mg monthly maintenance dosing, and can be self-administered▪ is a biologic disease-modifying anti-rheumatic drug (DMARD)▪ is an interleukin (IL)-17A inhibitor, whereas the alternative biologic DMARDs licensed for this indication are tumour necrosis factor (TNF)-alpha inhibitors• a homecare service is already established for secukinumab• the service plans to use secukinumab second-line or later, as an alternate option to biosimilar TNF-alpha inhibitors in patients with primary or secondary inefficacy to biosimilar TNF-alpha inhibitors• the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of secukinumab	
	<p>The Group accepted the restricted local need for secukinumab for the treatment of adults with active nr-axSpA, as outlined in SMC 2308.</p>	
	<p>SMC 2308 - Secukinumab 150mg solution for injection in pre-filled syringe, 150mg solution for injection in pre-filled pen (Cosentyx®) is routinely available in line with national guidance (SMC 2308).</p> <p>Indication under review: treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs.</p> <p>In a randomised phase III study, secukinumab, compared with placebo, significantly improved symptoms in adults with active non-radiographic axial spondyloarthritis.</p> <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.</p> <p>It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Secukinumab is intended for use under</p>	

PROTECTIVE MARKING: NONE

ITEM	SUBJECT	ACTION
	the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which secukinumab is indicated.	FTEAM

Items 8.5, 8.6 and 8.7 were taken together.

8.5. FG1SMC 2346 - ACALABRUTINIB (UNTREATED CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL) WITH 17P DELETION OR TP53 MUTATION)

8.6. FG1SMC 2348 - ACALABRUTINIB (RELAPSED/REFRACTORY CLL)

8.7. FG1SMC 2347 - ACALABRUTINIB (UNTREATED CLL WITHOUT 17P DELETION OR TP53 MUTATION)

Mr Paterson and Dr Fitton declared personal, non-specific interests in AstraZeneca UK Limited and took part in decision-making.

The Group considered three requests for acalabrutinib for the treatment of untreated and relapsed/refractory chronic lymphocytic leukaemia (CLL).

- April 2021, following two abbreviated submissions reviewed by the SMC executive, acalabrutinib was accepted for use within NHS Scotland:
Indication 1) as monotherapy for the treatment of adults with previously untreated CLL who have a 17p deletion or TP53 mutation and in whom chemo-immunotherapy is unsuitable (SMC 2346) and
indication 2) as monotherapy for the treatment of adults with relapsed/refractory CLL who have had at least one previous therapy, in whom chemo-immunotherapy is unsuitable (SMC 2348)
- June 2021, following a full submission, acalabrutinib was accepted for use within NHS Scotland; Indication 3) as monotherapy for the treatment of adult patients with previously untreated CLL without a del(17p) or TP53 mutation and who are ineligible for fludarabine, cyclophosphamide and rituximab (FCR) therapy (SMC 2347)
- acalabrutinib is a [second generation] Bruton's tyrosine kinase (BTK) inhibitor licensed and approved for use in NHS Scotland to treat CLL
- ibrutinib [first generation BTK inhibitor] is included on the formulary for relapsed/refractory CLL (SMC 1151/16) and as a first-line treatment of CLL in the presence of 17p deletion or TP53 mutation. Ibrutinib is not recommended for use in previously untreated CLL patients who do not have 17p deletion or TP53 mutation.
- acalabrutinib and ibrutinib are oral medications, that are taken until disease progression or unacceptable toxicity
- acalabrutinib is taken twice daily, and has less cardiac toxicity [than ibrutinib], in particular less risk of atrial fibrillation or arrhythmia, which is a consideration in those with pre-existing cardiac disease or cardiovascular risk factors
- there are more long term data on the effectiveness of ibrutinib, and ibrutinib has a once-a-day dosing regimen which is more convenient, and so remains a good option for patients without cardiovascular risk factors
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of acalabrutinib

The Group accepted the restricted local need for acalabrutinib for the treatment of CLL as outlined in SMC 2346, SMC 2347 and SMC 2348.

SMC 2346 - Acalabrutinib 100mg hard capsules (Calquence®) ▼ is routinely available in line with national guidance (SMC 2346).

Indication under review: as monotherapy for the treatment of adults with previously untreated chronic lymphocytic leukaemia (CLL) who have a 17p deletion or TP53 mutation and in whom chemo-immunotherapy is unsuitable.

Acalabrutinib offers an additional treatment choice in the therapeutic class of Bruton tyrosine kinase inhibitor in this setting.

ITEM	SUBJECT	ACTION
	<p>Another medicine within this therapeutic class has been accepted via the end of life and orphan medicine process.</p> <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 with this medicinal product should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.</p>	FTEAM
	<p>SMC 2348 - Acalabrutinib 100mg hard capsules (Calquence®) ▼ is routinely available in line with national guidance (SMC 2348).</p> <p>Indication under review: as monotherapy for the treatment of adults with relapsed/refractory chronic lymphocytic leukaemia (CLL) who have had at least one previous therapy, in whom chemo-immunotherapy is unsuitable. Acalabrutinib offers an additional treatment choice in the therapeutic class of BTK inhibitor in this setting.</p> <p>Another medicine within this therapeutic class has been accepted via the end of life and orphan medicine process.</p> <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 with this medicinal product should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.</p>	FTEAM
	<p>SMC 2347 - Acalabrutinib 100mg hard capsules (Calquence®) ▼ is routinely available in line with national guidance (SMC 2347).</p> <p>Indication under review: as monotherapy for the treatment of adults with previously untreated chronic lymphocytic leukaemia (CLL) without a 17p deletion or TP53 mutation and who are ineligible for fludarabine, cyclophosphamide and rituximab (FCR) therapy. Acalabrutinib, compared with chlorambucil-obinutuzumab, significantly improved progression-free survival in adults with previously untreated CLL with co-morbidities.</p> <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 with this medicinal product should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.</p>	FTEAM

Items 8.8 and 8.9 were taken together.

8.8. SBAR - NALOXEGOL (OPIOID INDUCED CONSTIPATION (OIC) IN PALLIATIVE CARE)

8.9. SBAR - NALDEMEDINE (OIC IN PALLIATIVE CARE)

There were no declarations of interest in Kyowa Kirin or Shionogi BV.

The Group considered the request from the Palliative Care Service for naloxegol and naldemedine, for the treatment of refractory opioid induced constipation (OIC) adults with chronic cancer pain whose constipation has not adequately responded to laxatives. The Group noted:

- naloxegol and naldemedine were accepted to formulary in January 2021 for the treatment of OIC in adults with chronic non-cancer pain

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- the Scottish Palliative Care Guidelines for constipation already include naloxegol, and naldemedine will be considered for inclusion at the August meeting
- the Palliative Care Service plans to use the same starting and stopping criteria as the gastrointestinal service
- prescribing or recommendation to prescribe will be in a limited number of patients, taking account of the advantages/disadvantages of each agent as well as the potential increased risk of gastrointestinal obstruction and therefore perforation in this patient group
- the costs of naloxegol and naldemedine are higher than other laxatives
- naloxegol is licensed to be crushed and administered through a nasogastric tube, which is not included in the licensing for naldemedine
- only naloxegol recommends stopping all laxatives before initiating treatment to allow assessment of treatment response
- naldemedine does not require a dose reduction in renal impairment, whereas for moderate and severe renal impairment, the starting dose of naloxegol should be reduced from 25mg to 12.5mg
- naldemedine can be taken with or without other laxatives

The Group accepted the local need for naloxegol and naldemedine in the management of refractory OIC in adults with chronic cancer pain. Acceptance is subject to inclusion in the prescribing protocol that is approved by the Medicine Guidelines and Policies Group.

Until the local prescribing protocol is published by the Medicines Guidelines and Policies Group, prescribing should remain within the managed service.

SMC 1106/15 - Naloxegol 12.5mg, 25mg film-coated tablets (Moventiq®) is routinely available in line with local guidance.

Indication under review: for the treatment of opioid-induced constipation in adults who have had an inadequate response to laxative(s).

Restriction: for the treatment of refractory opioid-induced constipation in adults with chronic cancer pain whose constipation has not adequately responded to at least two laxatives.

It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.

FTEAM

SMC 2242 - Naldemedine 200micrograms film-coated tablets (Rizmoic®) ▼ is routinely available in line with local guidance.

Indication under review: for the treatment of opioid-induced constipation in adults who have previously been treated with a laxative.

Restriction: for the treatment of refractory opioid-induced constipation in adults with chronic cancer pain whose constipation has not adequately responded to at least two laxatives.

It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.

FTEAM

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - JUNE 2021

The Group noted the SMC provisional advice issued June 2021.

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

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - JUNE 2021

The Group noted the SMC advice published June 2021.

Following publication of the non-submission statement for ramucirumab (Cyramza®) (SMC 2291), this medicine will not be included on the Grampian Joint Formulary for the

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ITEM SUBJECT

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indication in question.

FTEAM

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

- SMC 2329 trifluridine/tipiracil (Lonsurf®) (submission received)
- SMC 2331 nintedanib (Ofev®) (submission received)
- SMC 2336 mogamulizumab (Poteligeo®) ▼ (submission received)
- SMC 2338 baricitinib (Olumiant®) ▼ (submission expected)
- SMC 2352 vigabatrin (Kigabeg®) (submission expected)
- SMC 2353 Alacare® (5-aminolevulinic acid) (submission expected)

Local advice for these medicines and indications will be included in the June 2021 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'.

FTEAM

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM - NONE

12. DOCUMENTS FOR INFORMATION

The Group noted items 12.1 (Drug Safety Update May 2021) and 12.2 (MED watch e-news).

13. AOCB - NONE

DATE OF NEXT MEETING

Tuesday 20 July 2021 starting at 14.30 via Microsoft Teams.

CHAIRMAN'S SIGNATURE

DATE 20 JULY 2021