NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 16 November 2021 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms L Cameron	Ms M Galvin	
Ms A Davie	Dr J Newmark	
Ms F Doney		
Dr L Elliot		
Dr J Fitton		
Mrs G McKerron		
Professor J McLay (Chairman)		
Dr M Metcalfe (from item 6.1)		
Mrs L Montgomery		
Mrs K Neave		
Mrs S O'Beirne		
Mr M Paterson		
Mr R Sivewright		

IN ATTENDANCE
Ms Christine Hay, Formulary and Medicines Management Pharmacist
Mrs Anne Rembisz, Formulary Team administrator

ITEM	SUBJECT	ACTION
	The Chairman welcomed members, opened the meeting and noted that a quorum was present. The Chairman welcomed Mrs McKerron, Chief Nurse Corporate, who was attending her first meeting having joined the Group in October.	
1.	**APOLOGIES** Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 19 OCTOBER 2021** The Group accepted the draft note of the meeting subject to minor typographical changes, and correction of the declaration of interest for Mr Paterson to 'personal, non-specific'. The corrected final approved minute will be in the public domain within 21 days of approval.	**FD**
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.	**FTEAM**
4.2.	**JANUS KINASE (JAK) INHIBITORS (UPDATE)** Ms Doney reported that in view of the safety signal shown with tofacitinib the Rheumatology Service will cardiovascular disease risk assess anyone on JAK inhibitors.	
5.	**FORMULARY GROUP DECISIONS OCTOBER 2021 – PUBLISHED – 02/11/2021** Members ratified the decisions of the October 2021 meeting as published.	**FTEAM**

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6. NETFORMULARY/FORMULARY REVIEW

6.1. NICE (M)TA715 - ADALIMUMAB, ETANERCEPT, INFLIXIMAB AND ABATACEPT FOR TREATING MODERATE RHEUMATOID ARTHRITIS

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

The Group considered the information presented regarding NICE (Multiple) Technology Appraisal Guidance No 715 - Adalimumab, etanercept, infliximab and abatacept for treating moderate rheumatoid arthritis after conventional disease-modifying antirheumatic drugs (DMARDs) have failed.

The Group noted that:

- adalimumab, etanercept, infliximab and abatacept are included on the formulary for the treatment of severe rheumatoid arthritis in line with NICE (M)TA375
- Healthcare Improvement Scotland (HIS) advises that the recommendations of NICE (M)TA715 are as valid for Scotland as for England and Wales
- TA715 provides guidance on adalimumab, etanercept, infliximab and abatacept for treating moderate rheumatoid arthritis and partially updates TA375
- adalimumab, etanercept and infliximab are available as biosimilar medicines, and the current preferred biosimilars are Amgevita®, Benepali® and Remsima® respectively
- the Service supports extending the use of these biologic DMARDs to include moderate rheumatoid arthritis [in line with TA715]
- the use of biological DMARDs in moderate rheumatoid arthritis represents a new cost to rheumatology with minimal offset available from conventional DMARDs

The Group accepted the restricted local need for adalimumab, etanercept and infliximab for the treatment of adults with moderate rheumatoid arthritis, as outlined in TA715.

TA715 - Amgevita® ▼ (adalimumab 40mg solution for injection in pre-filled pen/syringe) and Benepali® (etanercept 50mg solution for injection in pre-filled pen/syringe) are routinely available in line with national guidance (TA715).
Indication under review: in combination with methotrexate, or in monotherapy when methotrexate is contraindicated, for the treatment of active, moderate (a disease activity score [DAS28] of 3.2 to 5.1) rheumatoid arthritis in adults whose disease is not controlled well enough on intensive therapy with two or more conventional disease-modifying antirheumatic drugs.
The companies provide adalimumab and etanercept at the same or lower prices than those agreed with the Commercial Medicines Unit.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. **FTEAM**

TA715 - Remsima® (infliximab 120mg solution for injection in pre-filled pen/syringe, 100mg powder for concentrate for solution for infusion) is routinely available in line with national guidance (TA715).
Indication under review: in combination with methotrexate for the treatment of active, moderate (a disease activity score [DAS28] of 3.2 to 5.1) rheumatoid arthritis in adults whose disease is not controlled well enough on intensive therapy with two or more conventional disease-modifying antirheumatic drugs.
The companies provide infliximab at the same or lower prices than those agreed with the Commercial Medicines Unit.
It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. **FTEAM**

TA715 – Abatacept solution for injection in pre-filled pen/syringe, powder for concentrate for solution for infusion (Orencia®) is not routinely available as not recommended for use in NHS Scotland (TA715).

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	Indication under review: in combination with methotrexate for the treatment of moderate rheumatoid arthritis in adults who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate or a tumour necrosis factor (TNF)-alpha inhibitor. Not routinely available as not recommended for use in NHS Scotland.	**FTEAM**

6.2. FORMULARY REVIEW - OSTEOPOROSIS SIGN 142

The Group considered the review of the current formulary choices for osteoporosis and the updated SIGN Guidance 142 (Management of osteoporosis and the prevention of fragility fractures).

Ms Hay confirmed that on discussion with the Rheumatology Service the following changes to the formulary were proposed:

- splitting the formulary into sections for the treatment of postmenopausal women, men, and glucocorticoid induced osteoporosis (GIOP)
- risedronate 35mg costs significantly more than alendronic acid 70mg, the dual-energy X-ray absorptiometry (DEXA) scan letters will now highlight treatment choice as alendronic acid rather than clinician choice oral bisphosphonate
- the preferred formulation of alendronic acid and risedronate is the weekly preparation for all indications regardless of licensing, and the Service supports removing the daily preparations from the formulary
- the Service does not recommend the use of ibandronic acid for osteoporosis due to its poor efficacy in reducing hip fractures, alendronic acid and risedronate are preferred. Ibandronic acid [for osteoporosis] should be removed from the formulary and those currently taking ibandronic acid should be referred for a repeat DEXA scan.
- in SIGN 142 zoledronic acid and teriparatide are considered first-choice agents for some patient groups. As both agents are available generically or as biosimilar medicines, the SMC [not recommended] advice, for these agents should not be deemed extant as the basis for decision-making has changed.
- the Service is already following the recommendations of SIGN 142 for the use of teriparatide in postmenopausal women. There is local agreement to adopt Movymia®▼ as the preferred biosimilar teriparatide injection, treatment will be available via a homecare arrangement and the maximum total duration of treatment with teriparatide is 24 months. New patients will be initiated on Movymia®▼ with Terrosa®▼ remaining on formulary for patients already established on treatment. Forsteo® will be removed from the formulary.
- strontium ranelate is currently included on the formulary only for post-menopausal women. There has been a significant price increase since strontium came back to market, increasing by almost £100 for 28 sachets (£49.97 to £149.91) which equates to an annual cost of £1,948.83. The Rheumatology Service rarely uses strontium ranelate for men or women however it is considered useful where other treatment options are not available. The Service recommends that strontium ranelate is included on the formulary, in line with licensing, for men at high risk of fracture as well as post-menopausal women.
- zoledronic acid 5mg solution for infusion is not currently included on the formulary for GIOP but the Rheumatology Service are currently using it for this patient group. Zoledronic acid is included in the SIGN guidance for patients with GIOP who are intolerant of oral bisphosphonates and those in whom adherence to oral therapy may be difficult. The Service recommends that zoledronic acid is included on the formulary, in line with SIGN 142.

The Group supported the position taken that the SMC advice for zoledronic acid and teriparatide should no longer be considered extant, and agreed to all of the recommended changes to the formulary.

The Formulary Team will liaise with colleagues in the Medicines Management Team to

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	enable information sharing regarding the formulary changes, and follow-up with the Rheumatology Service to confirm DEXA scanning capacity for patients requiring a change to treatment.	**FTEAM**
	SBAR - Ibandronic acid 150mg tablets, 3mg solution for injection is not routinely available as there is a preference for alternative medicines. **Indication under review: for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.** **Not routinely available as there is a local preference for alternative medicines.**	**FTEAM**
	The Group accepted the restricted local need for Movymia®▼ as a treatment option within treatment pathways for appropriate patients as identified by treating clinicians and subject to compliance with a biosimilar medicines prescribing framework. Terrosa®▼ will remain on formulary for existing patients until November 2023.	
	SBAR - Movymia®▼ 20micrograms/80microliters solution for injection (teriparatide) is routinely available in line with local guidance. **Indication under review: for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture.** **Restriction: as a treatment option within treatment pathways for appropriate patients as identified by treating clinicians and subject to compliance with a biosimilar medicines prescribing framework.** **It was classified 1b- available for restricted use under specialist supervision and 8b – recommended for hospital use only.** **Patients should receive supplemental calcium and vitamin D supplements if dietary intake is inadequate.** **The maximum total duration of treatment with teriparatide should be 24 months.** **The 24-month course of teriparatide should not be repeated over a patient's lifetime.**	**FTEAM**
	Biological medicines, including biosimlar medicines, should be prescribed by both generic and brand name and the trade name and batch number should be recorded on the patient's prescription, case record or other appropriate clinical system.	
	SBAR – Forsteo® is not routinely available as there is a preference for alternative medicines. **Indications under review:** **1) Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture (see section 5.1). In postmenopausal women, a significant reduction in the incidence of vertebral and non-vertebral fractures but not hip fractures has been demonstrated.** **2) Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture.** **Restriction: in line with SMC and HealthCare Improvement Scotland advice.** **Not routinely available as there is a preference for alternative medicines.**	**FTEAM**
	The Group accepted the restricted local need for strontium ranelate for the treatment of osteoporosis in men at high risk of fracture.	
	SBAR - Strontium ranelate Aristo 2g granules for oral suspension is routinely available in line with local guidance. **Indication under review: for the treatment of osteoporosis in men at high risk of fracture, for whom treatment with other medicinal products approved for the treatment of osteoporosis is not possible due to, for example, contraindications or intolerance.**	

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	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.	**FTEAM**
	The Group accepted the restricted local need for zoledronic acid 5mg infusion for the treatment of adults with GIOP at increased risk of fracture who are intolerant of oral bisphosphonates and those in whom adherence to oral therapy may be difficult.	
	SIGN 142 - Zoledronic acid 5mg solution for infusion is routinely available in line with national guidance (SIGN 142). **Indication under review: for the treatment of osteoporosis associated with long-term systemic glucocorticoid therapy in adults at increased risk of fracture who are intolerant of oral bisphosphonates and those in whom adherence to oral therapy may be difficult.** **It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only.**	**FTEAM**

7. OTHER BUSINESS

7.1. WORLD ANTIMICROBIAL AWARENESS WEEK 18 - 24 NOVEMBER 2021

The Chairman confirmed that World Antimicrobial Awareness Week (WAAW) starts on 18 November. The Antimicrobial Team will be publicising the event and the theme for 2021 is 'Spread Awareness, Stop Resistance' and the overall slogan is: Antimicrobials: Handle with care.

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2331 - NINTEDANIB (NON-IPF PROGRESSIVE FIBROSING ILD)

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

The Group considered the request for nintedanib for the treatment of adults with chronic fibrosing interstitial lung diseases (ILDs) with progressive phenotype other than idiopathic pulmonary fibrosis (IPF).

The Group noted that:

- nintedanib, as Ofev®:
  - is already on the formulary for IPF
  - [for this indication] was accepted for use in NHS Scotland following a full submission assessed under the orphan equivalent process and the output from the PACE process
  - [for this indication] reduced the decline in forced vital capacity
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of nintedanib
- currently there are no licensed treatment options for non-IPF progressive fibrosing ILDs, and treatment with nintedanib may delay or avoid use of corticosteroids
- implementation will use the existing infrastructure for administering and monitoring oral antifibrotics for IPF, however, if patient numbers increase significantly, extra resource will be needed
- patient numbers are expected to be small, but will be cumulative as median survival in this patient group is four years
- the Service plans to supply via a homecare arrangement
- nintedanib in this patient group represents a new cost, with minimal cost offset from displaced medicines used off-label
- all cases identified as suitable for treatment will be discussed at the local ILD multidisciplinary team meeting
- NICE advice, nintedanib for treating idiopathic pulmonary fibrosis [TA379] includes a stopping rule - treatment is stopped if disease progresses (a confirmed decline in

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percent predicted forced vital capacity (FVC) of 10% or more) in any 12-month period

Members requested clarification from the Respiratory Team if there is a plan to implement a stopping rule, and if yes what their stopping rule would be. **FTEAM**

The Group accepted the restricted local need for nintedanib, as the brand Ofev®, for the treatment of adults with non-IPF progressive fibrosing ILDs as outlined in SMC 2331.

SMC 2331 - Nintedanib 100mg, 150mg soft capsules (Ofev®) is routinely available in line with national guidance (SMC 2331).
Indication under review: in adults for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with progressive phenotype other than idiopathic pulmonary fibrosis (IPF).
Nintedanib, compared with placebo, slowed the decline in forced vital capacity (FVC) in adults with non-IPF progressive fibrosing ILD.
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 Patients 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 physicians experienced in the management of diseases for which nintedanib is approved. **FTEAM**

8.2. FG1SMC 2159 - FIXAPOST® (OPEN ANGLE GLAUCOMA AND OCULAR HYPERTENSION)

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

The Group considered the request for Fixapost® for the reduction of intraocular pressure in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues and who have proven sensitivity to preservatives.

The Group noted that:

- Fixapost®:
  - is the first preservative-free eye drop that contains the two topical ophthalmological agents - latanoprost (prostaglandin analogue) and timolol (beta-blocker)
  - provides an alternative to using the two medicines as separate preservative-free drops, i.e., Monopost® and Tiopex®
  - has the potential to improve patient compliance, as it is more convenient for patients to use a single combination product [rather than the individual components separately]
  - costs less than using the two preservative-free products individually
  - is more expensive than the preservative containing eye drops, but it will be reserved for those sensitive to preservatives

The Group accepted the restricted local need for the combination eye drop Fixapost® as outlined in SMC 2159.

SMC 2159 - Fixapost® 50micrograms/mL/5mg/mL preservative free eye drops (latanoprost/timolol) is routinely available in line with national guidance (SMC 2159).
Indication under review: for the reduction of intraocular pressure in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues and who have proven sensitivity to preservatives.

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The combination product costs less than preservative-free latanoprost and timolol eye drops administered separately but is more expensive than the equivalent generic multi-dose eye drop preparation with preservative.
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. **FTEAM**

8.3. FG1SMC 2362 - NIVOLUMAB (OESOPHAGEAL SQUAMOUS CELL CARCINOMA)

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

The Group considered the request for nivolumab as monotherapy for the treatment of adults with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based combination chemotherapy.

The Group noted that:

- nivolumab:
  - is currently included on formulary for multiple indications
  - is given every two weeks as an intravenous infusion over 30 mins
  - [for this indication] was accepted for use in NHS Scotland following a full submission assessed under the end of life and orphan equivalent medicine process and the output from the PACE process
- In the clinical trial, ATTRACTION-3:
  - patients were recruited that had a life expectancy of at least three months and an ECOG performance status of 0 or 1
  - the primary outcome of median overall survival was 10.9 months and 8.4 months for nivolumab and investigators choice respectively
  - key secondary outcomes were not supportive of the primary outcome, and favoured the investigators choice group; median progression free survival was 1.7 months and 3.4 months for nivolumab and investigators choice respectively
  - the median duration of treatment in the nivolumab and control group was 2.6 months but the overall survival rate at 18 months was 30% in the nivolumab group
- the delayed response onset of nivolumab should be considered before initiating treatment in patients with oesophageal squamous cell carcinoma. A higher number of deaths within 2.5 months after randomisation was observed with nivolumab compared to chemotherapy. No specific factor(s) associated with early deaths could be identified.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of nivolumab
- patient number are expected to be very small
- this will be a new spend, cost offset is available as patients receiving nivolumab would have previously received palliative chemotherapy with docetaxel or paclitaxel, both are available as generics

The Group accepted the restricted local need for nivolumab for the treatment of adults with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based combination chemotherapy as outlined in SMC 2362.

SMC 2362 Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) is routinely available in line with national guidance (SMC 2362).
Indication under review: as monotherapy for the treatment of adults with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based combination chemotherapy.
In a phase III study, treatment with nivolumab significantly improved overall survival compared with taxane chemotherapy in patients with unresectable

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advanced, recurrent or metastatic oesophageal squamous cell carcinoma.
This advice takes account of the views from a Patients and Clinician Engagement (PACE) meeting.
This advice applies only in the context of an approved NHS Scotland Patients 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 must be initiated and supervised by physicians experienced in the treatment of cancer. **FTEAM**

8.4. FG1SMC 2359 - AVELUMAB (UROTHELIAL CARCINOMA)

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

The Group considered the request for avelumab as monotherapy for the first-line maintenance treatment of adults with locally advanced or metastatic urothelial carcinoma who are progression-free following platinum-based chemotherapy.

The Group noted that:

- avelumab:
  - is already included on the formulary for the treatment of metastatic Merkel cell carcinoma
  - [for this indication] was accepted for use in NHS Scotland following a full submission assessed under the end of life and orphan equivalent medicine process, application of the appropriate SMC modifiers, and the output from the PACE process
  - [for this indication] is licensed and administered as an 800mg intravenous infusion every 2 weeks, which differs from the avelumab dose given in the clinical trial [JAVELIN Bladder 100; 10mg/kg once every 2 weeks]
  - in JAVELIN Bladder 100, the median duration of treatment in the avelumab group was 24.9 weeks (range 2 to 159.9)
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of avelumab
- patient numbers are expected to be small
- this will be a new cost, however there will be a degree of cost offset available from pembrolizumab used second-line on progression

The Group accepted the restricted local need for avelumab as monotherapy for the first-line maintenance treatment of adults with locally advanced or metastatic urothelial carcinoma who are progression-free following platinum-based chemotherapy as outlined in SMC 2359.

SMC 2359 - Avelumab 20mg/mL concentrate for solution for infusion (Bavencio®)▼ is routinely available in line with national guidance (SMC 2359).
Indication under review: as monotherapy for the first-line maintenance treatment of adults with locally advanced or metastatic urothelial carcinoma who are progression-free following platinum-based chemotherapy.
In a phase III study, maintenance treatment with avelumab plus best supportive care (BSC) significantly improved overall survival when compared to BSC alone.
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 and supervised by a physician experienced in the treatment of cancer. **FTEAM**

8.5. FG1SMC 2375 - PEMBROLIZUMAB (MSI-H OR DMMR COLORECTAL CANCER)

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

The Group considered the request for pembrolizumab as monotherapy for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in adults.

The Group noted that:

- the SMC applied a two-year stopping rule to the use of pembrolizumab for this indication, clinicians would submit an individual request if they feel it is medically necessary to continue treatment beyond two years
- pembrolizumab:
  - is already included on the formulary for a number of other indications
  - is given as an intravenous infusion at a dose of either 200mg every three weeks or 400mg every six weeks
- testing for MSI-H/dMMR tumour status using a validated test is recommended to select eligible patients
- the study, [KEYNOTE-177], found the beneficial effects of pembrolizumab were less favourable in the subgroup of patients with a KRAS/NRAS mutation and in patients with pulmonary only or pulmonary and hepatic metastases
- [for this indication] the median duration of treatment was 11.1 months
- this will be a new costs with minimal cost offset available from standard chemotherapy, e.g., FOLFOX (oxaliplatin/leucovorin/5-flurorouracil)
- patient numbers are expected to be very small

The Group accepted the restricted local need for pembrolizumab, as monotherapy for the first-line treatment of metastatic MSI-H or dMMR colorectal cancer in adults, as outlined in SMC 2375.

SMC 2375 - Pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda®) is routinely available in line with national guidance (SMC 2375).
Indication under review: as monotherapy for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in adults.
Restriction: treatment with pembrolizumab is subject to a two-year clinical stopping rule.
In an open-label, phase III study, pembrolizumab monotherapy was associated with significantly improved progression-free survival compared with investigator's choice of chemotherapy in patients with metastatic MSI-H/dMMR colorectal cancer.
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 must be initiated and supervised by specialist physicians experienced in the treatment of cancer. **FTEAM**

8.6. FG1SMC 2295 - ENTRECTINIB (ROZLYTREK®) (SOLID TUMOURS EXPRESSING A NTRK GENE FUSION)

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

The Group considered the information presented regarding entrectinib as monotherapy for the treatment of adult and paediatric patients 12 years of age and older with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion.

The Group noted that:

- the NTRK gene fusion testing required for this medicine is not performed locally and has a low capacity across Scotland, and the Consortium laboratories will not be able to increase capacity without additional funding

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- due to the need for increased capacity for this testing, a plan and strategies are required from the Scottish Government and the genetic testing laboratories so that entrectinib can be used for this indication

The Group supported the proposal to record entrectinib in line with SMC 2295 as not routinely available as implementation plans are being developed.

SMC 2295 - Entrectinib 100mg, 200mg hard capsules (Rozlytrek®)▼ is not routinely available as local implementation plans are being developed.
Indication under review: as monotherapy for the treatment of adult and paediatric patients 12 years of age and older with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion

- **who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and**
- **who have not received a prior NTRK inhibitor**
- **who have no satisfactory treatment options**

In a pooled analysis of three phase I/II studies in adults with metastatic or locally advanced NTRK fusion-positive solid tumours, 64% of patients achieved an objective response with entrectinib treatment. The median duration of response in these patients was 12.9 months. Positive objective response rate results were also reported in a phase I/Ib paediatric study.
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.
Not routinely available as local implementation plans are being developed. **FTEAM**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED NOVEMBER 2021

The Group noted the SMC provisional advice issued November 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 – PUBLISHED NOVEMBER 2021

The Group noted the SMC advice published November 2021.

Following publication of the negative SMC recommendation for selpercatinib (Retsevmo®)▼ SMC 2371 and the non-submission statements, for asfotase alfa (Strensiq®)▼ SMC 2433, durvalumab (Imfinzi®)▼ SMC 2434, olaparib (Lynparza®) SMC 2435 and olaparib (Lynparza®) SMC 2436, and sebelipase alfa (Kanuma®)▼ SMC 2437 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 2383 osimertinib (Tagrisso®)▼ (submission expected)
- SMC 2379 atezolizumab (Tecentriq®)▼ (submission expected)
- SMC 2380 pembrolizumab (Keytruda®) (submission received)
- SMC 2410 bimekizumab (Bimzelx®)▼ (submission expected)
- SMC 2384 ponesimod (Ponvory®)▼ (submission received)

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

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11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM

Nil of note.

12. DOCUMENTS FOR INFORMATION

12.1. MARKETING AUTHORISATION WITHDRAWN DAPAGLIFLOZIN 5MG (TYPE 1 DIABETES MELLITUS)

The Group noted that:

- effective 25th October 2021, dapagliflozin 5mg is no longer authorised for the treatment of patients with type 1 diabetes mellitus (T1DM) and should no longer be used in this population. This is based on AstraZeneca's decision to remove the T1DM indication for dapagliflozin 5mg.
- the removal of the T1DM indication is not due to any safety concern for dapagliflozin in any indication, including T1DM
- dapagliflozin 5mg for T1DM is accepted by SMC but is non-formulary; the diabetic service did not request formulary inclusion. The formulary will be updated to 'licence has been withdrawn' for the T1DM indication.
- dapagliflozin 5mg tablets remains on formulary for type 2 diabetes mellitus and/or symptomatic chronic heart failure with reduced ejection fraction in adults with severe hepatic impairment (a starting dose of 5mg is recommended. If well tolerated, the dose may be increased to 10mg).

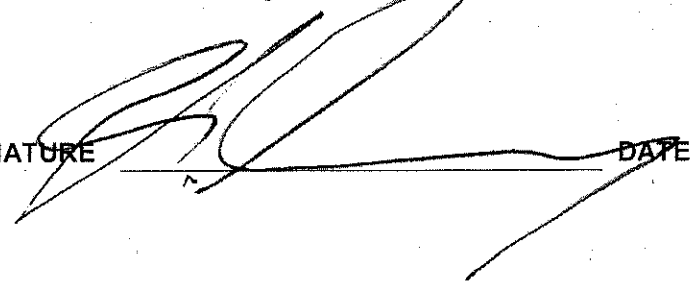
Effective 25th October 2021 dapagliflozin 5mg is no longer authorised for the treatment of patients with type 1 diabetes mellitus (T1DM) and should no longer be used in this population. This is based on AstraZeneca's decision to remove the T1DM indication for dapagliflozin 5mg.
SMC 2185 - Dapagliflozin 5mg is not routinely available in NHS Grampian.
Indication: adults for the treatment of insufficiently controlled type 1 diabetes mellitus as an adjunct to insulin in patients with BMI ≥27kg/m², when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy.
Not routinely available in NHS Grampian. FTEAM

13. AOCB

None.

DATE OF NEXT MEETING

Tuesday 21 December 2021 starting at 14.30 via Microsoft Teams.



CHAIRMAN'S SIGNATURE _____ **DATE 21 DECEMBER 2021**