NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 18 August 2020 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms F Doney	Ms A Davie	
Dr L Elliot (Chair)	Mrs L Harper	
Dr J Fitton	Professor J McLay	
Ms M Galvin	Mrs L Montgomery	
Mrs K Neave		
Mr M Paterson (from item 6.1)		
Mr C Rore		
Mr R Sivewright		
Dr A Sun (from item 8.5)		

IN ATTENDANCE
Ms Caitlin Wilkinson, Formulary Team administrator.

ITEM	SUBJECT	ACTION

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

WELCOME TO NEW MEMBER
The Chair welcomed Mrs Kirsty Neave to the Group. Mrs Neave joins the Group as a representative for the Pharmacy and Medicines Directorate Medicines Management Team.

The Chair noted this was the first Formulary Group meeting since February 2020.

1. APOLOGIES

Apologies for absence were requested and noted.

2. MINUTE FROM PREVIOUS MEETING - NONE

It was confirmed that the February meeting note was approved at the March Executive decision-making Group meeting.

3. PRESENTATION - NONE

4. MATTERS ARISING

4.1. TRIENTINE DIHYDROCHLORIDE

Ms Doney confirmed that there is an expectation that by the end of the year a licensed trientine dihydrochloride product will be marketed in the UK. When available it will replace the use of an unlicensed product.
The Formulary Team will monitor availability and add this item to the action log. **FTEAM**

4.2. ACTION LOG (FROM MARCH 2020 MEETING)

The Group noted the action log from the March meeting papers.

The Chair confirmed that the meeting action log has been on hold since March, some items were progressed during the interim governance arrangements.

Ms Doney confirmed that the action log will be reinstated from this meeting and updated for the September meeting. **FTEAM**

4.3. FORMULARY GROUP REGISTER FOR CONFLICTS OF INTEREST

The Group reviewed the proposed summary register of conflicts of interest.

ITEM	SUBJECT	ACTION

Ms Doney confirmed that:

- the final approved register will be published on the Formulary Group intranet site
- the current information will be checked and updated before publication
- members are requested to review and if supportive approve the proposed format
- the updated register will be available for the September meeting to allow a final check before publication

Members noted the content of the summary register for conflicts of interest, and approved the format of the summary register. **FTEAM**

5. FORMULARY GROUP DECISIONS JULY 2020 – PUBLISHED – 3 AUGUST 2020

5.1. FORMULARY GROUP DECISIONS JULY 2020

Members ratified the decisions of the July 2020 Executive Group meeting as published.

6. NETFORMULARY/FORMULARY REVIEW

6.1. INFLIXIMAB SUBCUTANEOUS PREPARATION (REMSIMA®) - EXTENSION TO LICENCE

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

At the June meeting of the Executive decision-making Group a new subcutaneous formulation of biosimilar infliximab, Remsima®, was accepted to formulary as a maintenance treatment option for the management of rheumatoid arthritis in adults.

Ms Doney confirmed that additional licences' have been granted and the Gastroenterology department has requested inclusion on the formulary for adult patients with Crohn's disease and ulcerative colitis.

The Group noted:

- infliximab, as the intravenous formulation, is already included on the formulary for several licensed indications including rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriasis etc.
- infliximab as the subcutaneous preparation Remsima®:
  - is only licensed in adults, and as a maintenance treatment option, with a fixed dose maintenance regimen (120mg once every 2 weeks)
  - will be included in the re-tendering process when the current National Procurement framework expires
  - [in Gastroenterology] would be restricted to use as maintenance in line with the current formulary positioning, i.e. NICE guidance
  - requires initial loading with infliximab intravenous infusion, or patients to be established on intravenous infliximab before moving to the subcutaneous administration
- information regarding switching patients from the subcutaneous formulation to the intravenous formulation is not available
- information regarding switching patients from higher doses of intravenous infliximab (e.g. higher than 5mg/kg for Crohn's disease every 8 weeks) is not available
- access to a subcutaneous preparation would be beneficial for some patients

The Group noted the differences between the licensing of the intravenous and subcutaneous infliximab preparations [not licensed in paediatrics, and only as a maintenance preparation] and the lack of data for use following higher doses of intravenous infliximab.

The Group accepted the restricted local need within gastroenterology for subcutaneous infliximab, as a maintenance treatment option for Crohn's disease and ulcerative colitis in adults, in line with the current formulary approval for intravenous infliximab.

ITEM	SUBJECT	ACTION
	Remsima® 120mg solution for injection in pre-filled syringe, pre-filled pen is routinely available in line with local guidance. **Indication under review: in line with current formulary approval for intravenous infliximab for the maintenance treatment of adult patients with:** • **severe active Crohn's disease whose disease has not responded to conventional therapy, or who are intolerant of or have contraindications to conventional therapy** • **active fistulising Crohn's disease whose disease has not responded to conventional therapy, or who are intolerant of or have contraindications to conventional therapy** **Restriction: only for the maintenance treatment of adults with Crohn's disease in line with SMC and Healthcare Improvement Scotland advice for the reference intravenous infliximab product (TA187).** **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 qualified physicians experienced in the diagnosis and treatment of conditions for which it is indicated. Patients should be given the package leaflet and the patient reminder card. Instruction for use is provided in the package leaflet.**	**FTEAM**
	Remsima® 120mg solution for injection in pre-filled syringe, pre-filled pen is routinely available in line with local guidance. **Indication under review: in line with the current formulary approval for intravenous infliximab for the maintenance treatment of moderately to severely active ulcerative colitis in adults whose disease has responded inadequately to, is intolerant of or has contraindications to conventional therapy.** **Restriction: only for the maintenance treatment of adults with ulcerative colitis in line with SMC and Healthcare Improvement Scotland advice for the reference infliximab intravenous infusion product (TA329).** **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 qualified physicians experienced in the diagnosis and treatment of conditions for which it is indicated. Patients should be given the package leaflet and the patient reminder card. Instruction for use is provided in the package leaflet.**	**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.	
7.	**OTHER BUSINESS**	
	7.1. NATIONAL CANCER MEDICINES ADVISORY GROUP (NCMAG) INTERIM GOVERNANCE ARRANGEMENTS FOR CANCER MEDICINES IN ADULTS DURING COVID-19	
	Ms Galvin discussed the SBAR outlining the National Cancer Medicines Advisory Group (NCMAG) interim governance arrangements for cancer medicines in adults during COVID-19 and a proposal for review and ratification of the NCMAG recommendations. Ms Galvin confirmed that: • the governance framework outlines the interim arrangements [in NHS Scotland] for oversight of proposed changes to adult Systemic Anti-Cancer Therapy (SACT) practice in the context of COVID 19 • medicines/regimens not included on the formulary or accepted by NCMAG will be considered using the local non-formulary processes • NCMAG approvals will be discussed at the bimonthly NHS Grampian SACT Group meetings with the minutes being forwarded to the Area Drug and Therapeutics Committee (ADTC) for formal ratification within the Health Board	

ITEM	SUBJECT	ACTION

- NCMAG advice has been implemented locally
- the development of NCMAG has been positively received by cancer centres. It has facilitated rapid decision-making and collaboration between different cancer centres.
- the process is not without risk – the group was convened quickly and the financial implications of the interim treatments have not been considered.
  When advice is published there is no financial information provided for Health Boards. A budget impact tool has now been introduced, however Boards are required to compile data and populate the tool to support consideration of the financial implications of the new protocols/treatments.
- new ChemoCare protocols have been created to identify patients that are treated under NCMAG advice

The Group noted the implementation requirements highlighted in the Interim Governance Framework:

- All cancer networks and Boards are expected to ensure practice is aligned to the advice from the group unless there are exceptional circumstances
- Regional Cancer network lead to:
  - cascade the decision and links to associated documents to their constituent boards
  - inform the Chemotherapy Electronic Prescribing and Administration System clinical support team(s)
- NHS Boards to:
  - act on the decisions and advice from the national group and ensure relevant staff are aware of the decisions
  - cascade information and links to associated documents through local SACT groups and teams

The Group noted the Board's obligations, including responsibility to review/compile the financial implications. The need for timely introduction and effective two-way communication was emphasised, and the Group considered that the Grampian Area Drug and Therapeutics Committee (GADTC) should consider if there are any additional governance issues related to the financial and communication risks within this process.

Ms Doney noted the SBAR recommends that information would come to the Formulary Group for ratification, however due to the governance concerns this should be escalated to the GADTC in the first instance.

The Group backed the recommendations in the Interim Governance Framework, and supported the SBAR in principle, but considered that information should be escalated to the GADTC to highlight the financial and communication risks that are inherent within the process. Ms Doney will progress this item. **FD**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2238 - ENCORAFENIB IN COMBINATION WITH BINIMETINIB (MELANOMA)

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

The Group considered the request for encorafenib in combination with binimetinib for the treatment of adult patients with unresectable or metastatic melanoma with BRAF V600 mutation.

The Group noted:

- encorafenib used in combination with binimetinib:
  - meets SMC end of life and orphan equivalent criteria
  - [for this indication] was accepted for use in NHS Scotland following the output from the PACE process, and application of the appropriate SMC modifiers
  - would replace an alternative combination regimen, trametinib plus dabrafenib
  - is not restricted to first-line, whereas the alternative combination treatment option is

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limited to first-line use only

- a significant side effect difference is pyrexia – *pyrexia being more common with trametinib plus dabrafenib*
- [when used first-line] cost off-set will be available against the alternative BRAF/MEK combination option
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of encorafenib in combination with binimetinib
- the service has limited experience with the new combination
- standard therapy is now dual therapy not monotherapy
- there are no clinical trials currently open for this patient group

The Group accepted the restricted local need for encorafenib in combination with binimetinib for the treatment of adult patients with unresectable or metastatic melanoma with BRAF V600 mutation, in line with SMC 2238.

SMC 2238 - Encorafenib 50mg, 75mg hard capsules (Braftovi®) ▼ is routinely available in line with national guidance (SMC 2238).
Indication under review: in combination with binimetinib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.
Progression-free survival was significantly longer in the encorafenib plus binimetinib group compared with BRAF inhibitor monotherapy in a phase III study of patients with unresectable or metastatic BRAF V600 melanoma.
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.
This advice takes account of 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. Encorafenib treatment in combination with binimetinib should be initiated and supervised under the responsibility of a physician experienced in the use of anticancer medicinal products. **FTEAM**

SMC 2238 - Binimetinib 15mg film-coated tablets (Mektovi®) ▼ is routinely available in line with national guidance (SMC 2238).
Indication under review: in combination with encorafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.
Progression-free survival was significantly longer in the encorafenib plus binimetinib group compared with BRAF inhibitor monotherapy in a phase III study of patients with unresectable or metastatic BRAF V600 melanoma.
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.
This advice takes account of 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. Binimetinib treatment in combination with encorafenib should be initiated and supervised under the responsibility of a physician experienced in the use of anticancer medicinal products. **FTEAM**

The Group noted that dual therapy is now the preferred first-line treatment option for this patient group. As vemurafenib monotherapy is no longer used first-line the Group supported removal from the formulary.

There were no conflicts of interest recorded in relation to vemurafenib.

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	SMC 792/12 - Vemurafenib 240mg film-coated tablet (Zelboraf®) is not routinely available as there is a local preference for alternative medicines. **Indication under review: as monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.** **Restriction: for use in the first-line treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma.** **Not routinely available as there is a local preference for alternative medicines.**	**FTEAM**

ITEMS 8.2 TO 8.6

The Group considered five submissions for medicines used in the treatment of non-small cell lung cancer (NSCLC). The Chair confirmed that lung cancer is the leading cause of cancer-related death in men and women in developed countries, and it is the second leading cause of cancer-related death in less developed countries. NSCLC represents approximately 85% of all lung cancers, and the majority of patients present with locally advanced or metastatic disease.

8.2. FG1SMC 2147 - BRIGATINIB (ALK-POSITIVE ADVANCED NSCLC)

8.3. FG1SMC 2239 - LORLATINIB (ALK-POSITIVE ADVANCED NSCLC)

Items 8.2 to 8.3 were taken together.

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

The Group noted:

- anaplastic lymphoma kinase (ALK) positive NSCLC is a rare form of lung cancer with ALK gene rearrangements occurring in approximately 5% of patients with NSCLC. ALK-positive disease is more common in younger patients, with adenocarcinoma histology who have never smoked.
- brigatinib and lorlatinib
  - were accepted by SMC subject to the output from PACE meetings, the application of the appropriate SMC modifiers and the availability of Patient Access Schemes that improve the cost-effectiveness of treatment
  - are oral targeted treatment options
- brigatinib:
  - meets SMC end of life and ultra-orphan criteria
  - is a tyrosine kinase inhibitor (TKI) that targets ALK, c-ros oncogene 1 (ROS1), and insulin-like growth factor 1 receptor (IGF-1R)
  - is the fourth TKI licensed for the treatment of ALK-positive NSCLC
  - has a very narrow indication, as it is only licensed for use in patients previously treated with crizotinib
  - will be required for a very small number of patients, but patients may receive treatment for a few years - median duration of exposure in the trial was 21.8 months
- lorlatinib
  - has a conditional marketing authorisation from the European Medicines Agency and meets SMC end of life criteria for this indication
  - is a selective, adenosine triphosphate (ATP)-competitive inhibitor of ALK and c-ros oncogene 1 (ROS1) tyrosine kinases
  - was accepted for interim use in NHS Scotland, subject to ongoing evaluation and future reassessment by SMC
  - would compete with/replace ceritinib as a second-line treatment option
  - trial data showed a difference in response between Asian and non-Asian patients, so the overall response rate may overestimate the efficacy for the Scottish population (38% of trial patients were Asian)

- alectinib is the current first-line TKI for this patient group
- ALK-positive patient numbers would be small. However, patients that respond to targeted therapy can remain on treatment for several years.
- the service would like to have second-/third-line targeted treatment options available
- there is the potential for a 'super-responder' with all of the ALK TKI therapies

The Group accepted the restricted local need for brigatinib, as monotherapy for the treatment of adult patients with ALK-positive advanced NSCLC previously treated with crizotinib, in line with SMC 2147.

SMC 2147 - Brigatinib 30mg, 90mg, 180mg film-coated tablets (Alunbrig®) ▼ is routinely available in line with national guidance (SMC 2147).
Indication under review: as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.
Brigatinib was associated with an objective response rate of 56% in a single-arm, open-label, phase II study in patients with ALK-positive NSCLC who had progressed on first-line targeted treatment with crizotinib. This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of brigatinib and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. This advice takes account of 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 with brigatinib should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. **FTEAM**

The Group accepted the restricted local need for lorlatinib as monotherapy for the treatment of adult patients with ALK-positive advanced NSCLC whose disease has progressed after alectinib or ceritinib as the first ALK TKI therapy; or crizotinib and at least one other ALK TKI, in line with SMC 2239.

SMC 2239 - Lorlatinib 25mg, 100mg film-coated tablets (Lorviqua®) ▼ is routinely available in line with national guidance, on an interim basis subject to ongoing evaluation and future reassessment (SMC 2239).
Indication under review: as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after:

- **alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or**
- **crizotinib and at least one other ALK TKI**

In the relevant subgroup of a non-comparative phase I/II study of previously-treated patients with ALK positive advanced NSCLC, lorlatinib was associated with an objective response rate of approximately 40%.
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 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 with lorlatinib should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. **FTEAM**

8.4. FG1SMC 2184 - DACOMITINIB (LOCALLY ADVANCED OR METASTATIC NSCLC)

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

ITEM	SUBJECT	ACTION

The Group considered the request for dacomitinib as monotherapy, for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with epidermal growth factor receptor (EGFR)-activating mutations.

The Group noted:

- dacomitinib:
  - is a second generation EGFR tyrosine kinase inhibitor
  - [for this indication] meets SMC orphan equivalent and end of life criteria
  - is accepted [by SMC] as a first-line treatment option
  - showed a 5.5 month improvement in median progression-free survival (PFS) compared to gefitinib (14.7 months [95% CI: 11.1, 16.6] vs. 9.2 months [95% CI: 9.1, 11.0]). However subgroup analyses for PFS showed inconsistent results for patients >75 years and non-Asian patients.
- the study included a significant proportion of Asian patients (77%). Overall, the superiority of dacomitinib over gefitinib was not observed in the subset of non-Asian population [in non-Asian patients, median PFS was 9.3 months for dacomitinib versus and 9.2 months for gefitinib]. Nevertheless, a literature review indicated that there is no consistent pattern that would suggest that non-Asian patients respond differently from Asian patients to this class of drug.
- the median duration of treatment was 66.7 weeks
- gefitinib was the comparator in the study, however this does not represent current clinical practice
- afatinib is currently the preferred first-line choice. In clinical practice, patients cannot maintain the recommended starting dose of afatinib [40mg daily, up to 50mg daily]. Patients are often maintained on 20mg daily due to adverse effects – particularly diarrhoea.
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of dacomitinib
- the service has no experience in the use of dacomitinib, but is keen to have it available to see if there is an improvement in adverse events, and if patients can be maintained at the recommended treatment dose
- the flat-pricing structure for both afatinib and dacomitinib
- cost offset is available from the displacement of first-line afatinib

Ms Doney queried if there is a need for gefitinib in the first-line setting. Ms Galvin supported removing gefitinib from formulary and will raise this with the service. **MG**

The Group accepted the restricted local need for dacomitinib as monotherapy, for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR-activating mutations.

SMC 2184 - Dacomitinib 15mg, 30mg, 45mg film-coated tablets (Vizimpro®) ▼ is routinely available in line with national guidance (SMC 2184).
Indication under review: as monotherapy, for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR)-activating mutations.
In an open-label, randomised, phase III study, dacomitinib significantly improved progression-free survival compared with another EGFR tyrosine kinase inhibitor in adults with locally advanced or metastatic NSCLC with EGFR-activating mutations.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of dacomitinib and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment with dacomitinib should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. **FTEAM**

ITEM	SUBJECT	ACTION

The Group supported removal of gefitinib from the formulary, pending advice from the service.

Mr Paterson and Dr Fitton declared personal, non-specific interests in Astra Zeneca, and took part in decision-making.

SMC 615/10 - Gefitinib 250mg film-coated tablets (Iressa®) is not routinely available as there is a local preference for alternative medicines.
Indication under review: for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of epidermal growth factor receptor tyrosine kinase (EGFR-TK).
Not routinely available as there is a local preference for alternative medicines. **FTEAM**

Items 8.5 to 8.6 were taken together.

8.5. FG1SMC 2187 - PEMBROLIZUMAB (IN COMBINATION WITH CARBOPLATIN AND PACLITAXEL FOR METASTATIC SQUAMOUS NSCLC)

8.6. FG1SMC 2207 - PEMBROLIZUMAB (IN COMBINATION WITH PEMETREXED AND PLATINUM CHEMOTHERAPY FOR METASTATIC NON-SQUAMOUS NSCLC)

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

The Group considered two requests for pembrolizumab, added to current first-line doublet chemotherapy for patients with metastatic NSCLC in adults whose tumours express programmed death ligand 1 (PD-L1) with a <50% tumour proportion score (TPS).

The Group noted:

- pembrolizumab:
  - is a humanised monoclonal antibody which blocks the interaction between the programmed death-1 (PD-1) receptor and its ligands PD-L1 and PD-L2
  - [for both indications] was accepted for use in NHS Scotland following the output from PACE meetings, application of SMC modifiers and treatment [with pembrolizumab] is subject to a two-year clinical stopping rule
  - meets SMC end of life criteria [for both indications]
  - is currently approved first-line for metastatic NSCLC in patients whose PD-L1 TPS is ≥50%
- the two requests extend use to patients with a <50% TPS, or where it has not been possible to evaluate PD-L1 TPS
- the addition of pembrolizumab to standard doublet chemotherapy was associated with a statistically significant improvement in progression-free survival and overall survival
- use of pembrolizumab in these patient groups represents an additional cost to the service. Some deferred offset may be available from reduced use of checkpoint inhibitors in the second-line setting.
- higher side effects are expected with triplet therapy, and it is expected that treatment would be limited to 'fitter' patients [ECOG-PS 0 to 1]
- the SMC advice take account of the benefits of a PAS that improves the cost-effectiveness of pembrolizumab
- the risk of dosing errors with the different regimens available for pembrolizumab

Ms Galvin confirmed that:

- the NCMAG issued interim advice accepting pembrolizumab as monotherapy for the first-line treatment of metastatic NSCLC in adults whose tumours express PD-L1 with a 1 to 49% TPS, with no EGFR or ALK positive tumour mutation. While the interim advice is available pembrolizumab monotherapy may be preferred to triple therapy.
- in non-squamous NSCLC patients, pembrolizumab would be used in combination with maintenance pemetrexed, not in place of pemetrexed maintenance

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	The Group accepted the restricted local need for pembrolizumab in combination with carboplatin and paclitaxel, for the first-line treatment of metastatic squamous NSCLC in line with SMC 2187.	
	SMC 2187 - Pembrolizumab 25mg/mL concentrate for solution for infusion, 50mg powder for concentrate for solution for infusion (Keytruda®) is routinely available in line with national guidance (SMC 2187). **Indication under review: in combination with carboplatin and paclitaxel for the first-line treatment of metastatic squamous non-small cell lung cancer (NSCLC) in adults.** **Restriction: in patients whose tumours express programmed death ligand 1 (PD-L1) with a <50% tumour proportion score (TPS), or in those whom it has not been possible to evaluate PD-L1 TPS. Treatment with pembrolizumab is subject to a two-year clinical stopping rule.** **Pembrolizumab in combination with platinum based doublet chemotherapy was associated with a progression-free survival and overall survival benefit over platinum based doublet chemotherapy in patients with treatment naïve metastatic squamous NSCLC.** **This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pembrolizumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.** **This advice takes account of 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. Therapy must be initiated and supervised by specialist physicians experienced in the treatment of cancer.**	**FTEAM**
	The Group accepted the restricted local need for pembrolizumab in combination with pemetrexed and platinum chemotherapy, for the first-line treatment of metastatic non-squamous NSCLC, in line with SMC 2207.	
	SMC 2207 - Pembrolizumab 25mg/mL concentrate for solution for infusion, 50mg powder for concentrate for solution for infusion (Keytruda®) is routinely available in line with national guidance (SMC 2207). **Indication under review: in combination with pemetrexed and platinum chemotherapy, for the first-line treatment of metastatic non-squamous non-small cell lung carcinoma (NSCLC) in adults whose tumours have no EGFR or ALK positive mutations.** **Restriction: in patients whose tumours express programmed death ligand 1 (PD-L1) with a <50% tumour proportion score (TPS), or in those whom it has not been possible to evaluate PD-L1 TPS. Treatment with pembrolizumab is subject to a two-year clinical stopping rule.** **The addition of pembrolizumab to pemetrexed and platinum chemotherapy significantly improved progression-free survival and overall survival in patients with metastatic non-squamous NSCLC with no EGFR or ALK mutations.** **This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pembrolizumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a 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. Therapy must be initiated and supervised by specialist physicians experienced in the treatment of cancer.**	**FTEAM**

ITEM	SUBJECT	ACTION

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – AUGUST 2020

The Group noted the SMC provisional advice issued August 2020.

The Chair confirmed that the SMC has remobilised and issued 15 SMC provisional detailed advice documents.

Ms Doney confirmed that andexanet alfa, a reversal agent for apixaban and rivaroxaban, will be scheduled for discussion at the September meeting. Dr Henry Watson, Consultant Physician, will be invited to discuss the medicine. **FTEAM**

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS – AUGUST 2020

The Group noted the SMC advice published August 2020.

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

- SMC 2251 neratinib (Nerlynx®) ▼(submission received)
- SMC 2271 hydroxycarbamide oral solution (Xromi®) (submission expected)

Local advice for these medicines and indications will be included in the August 2020 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'.

VEDOLIZUMAB 108MG SOLUTION FOR INJECTION IN PRE-FILLED PEN, PRE-FILLED SYRINGE (ENTYVIO®)

The Group ratified the decisions of the June 2020 Executive decision-making Group meeting for vedolizumab 108mg solution for injection in pre-filled pen/syringe (Entyvio®), noting that use is limited to maintenance treatment only. This position affects SMC 2276 and SMC 2277.

SMC 2276 - Vedolizumab 108mg solution for injection in pre-filled pen, pre-filled syringe (Entyvio®) is routinely available in line with local guidance.
Indication under review: for the maintenance treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNF-alpha) antagonist.
Patients who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse.
This advice takes account of the benefits of a confidential pricing arrangement and is contingent upon the continuing availability of the arrangement or a list price that is equivalent or lower. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be initiated and supervised by specialist healthcare professionals experienced in the diagnosis and treatment of ulcerative colitis. Patients should be given the package leaflet (and the Patient Alert Card). **FTEAM**

SMC 2277 - Vedolizumab 108mg solution for injection in pre-filled pen, pre-filled syringe (Entyvio®) is routinely available in line with local guidance.
Indication under review: for the maintenance treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a tumour necrosis factor-alpha antagonist.
Patients who continue treatment should be reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. For people in

ITEM	SUBJECT	ACTION
	complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. **This advice takes account of the benefits of a confidential pricing arrangement and is contingent upon the continuing availability of the arrangement or a list price that is equivalent or lower. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be initiated and supervised by specialist healthcare professionals experienced in the diagnosis and treatment of Crohn's disease. Patients should be given the package leaflet (and the Patient Alert Card).**	FTEAM

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM – AUGUST 2020

None.

12. DOCUMENTS FOR INFORMATION

Item 12.1 (Drug Safety Update July 2020)
Ms Doney highlighted the article *"systemically administered VEGF pathway inhibitors: risk of aneurysm and artery dissection"* and confirmed that the article has been shared with the Specialist services.

Item 12.2 (Grampian Primary Care Prescribing Group minute – January 2020), item 12.3 (Grampian Primary Care Prescribing Group minute – May 2020) and item 12.4 (Grampian Primary Care Prescribing Group minute – June 2020) were noted.

13. AOCB - NONE

DATE OF NEXT MEETING

Tuesday 15 September 2020 starting at 14.30 via Microsoft Teams.

CHAIR'S SIGNATURE LPElliot **DATE 15 SEPTEMBER 2020**