NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 19 November 2019 at 14:30 in the Seminar Room, David Anderson Building

PRESENT	APOLOGIES	APPROVED
Ms A Davie		
Ms F Doney		
Dr L Elliot		
Dr J Fitton		
Ms M Galvin		
Mrs L Harper (from item 3.1)		
Dr A MacDonald		
Professor J McLay (Chairman)		
Mrs L Montgomery		
Dr W Moore (from item 3.1)		
Mr M Paterson		
Mr R Sivewright (until item 10)		
Dr A Sun (from item 3.1)		

IN ATTENDANCE

Dr Saravanakumar Kanakarajan, Consultant in Anaesthesia and Pain Medicine, Aberdeen Royal Infirmary (ARI) for items 3.1 and 8.1.
Dr Gavin Preston, Consultant Haematologist, ARI for item 3.2.

Note some items were taken outwith the agenda running order.

ITEM	SUBJECT	ACTION
	The Chairman welcomed members, opened the meeting and noted that a quorum was present. The Chairman reminded members that, to assist preparation of the meeting note and ensure decisions are accurately recorded, the meeting would be recorded digitally. As soon as the minute is "approved" the relevant MP3 file will be deleted. Members consented to recording the meeting.	
1.	**APOLOGIES** Apologies for absence were requested and noted.	
2.	**DRAFT MINUTE OF THE MEETING HELD 17 SEPTEMBER 2019** The Group accepted the draft note of the meeting subject to minor typographical changes. The corrected final approved minute will be in the public domain within 21 days of approval.	**FD**
3.	**PRESENTATION**	
	3.1. SUBMISSION FOR TAPENTADOL AND UPDATED SIGN 136 (GUIDELINE FOR CHRONIC PAIN) Dr Saravanakumar Kanakarajan, Consultant in Anaesthesia and Pain Medicine, provided the Group with an informative presentation on the updated SIGN guideline and the proposed local positioning of tapentadol for the management of severe non-malignant chronic pain. Dr Kanakarajan confirmed that: • SIGN 136 Management of chronic pain, first issued in 2013, provides recommendations on the assessment and management, in non-specialist settings, of adults with chronic non-malignant pain. The guideline is not limited to pharmacological management.	

- in 2019 the section on opioids was updated, significantly reducing the dose at which review and assessment are required and recommending a new high limit of 90mg/day morphine-equivalent.
- SIGN 136 recommends that:
  - all patients receiving opioid doses of >50mg/day morphine equivalent should be reviewed regularly (at least annually) to detect emerging harms and consider ongoing effectiveness
  - pain specialist advice or review should be sought at doses >90mg/day morphine equivalent
- the specialist service provides generic advice on the internet about titrating up and down the dosages of opioids as well as education sessions for Primary Care physicians, due to the fact the service might struggle to review all patients on doses over 90mg/day of morphine equivalent
- in 2011, a paper quantified the number of opioid-related deaths in relation to the daily dose of morphine [in non-malignant pain]. The paper showed that the risk of death, for no other reason, increases with the daily dose of morphine [in milligrams]. An average daily dose of 200mg morphine (or equivalent) was associated with an almost three-fold increase [odds ratio 2.88] in the risk of opioid-related mortality. Doses from 20 – 49mg showed an increased odds ratio of 1.32; doses from 50 – 99mg showed an increased odds ratio of 1.92; doses from 100 – 199mg showed an increased odds ratio of 2.04.
- opioid awareness messages highlight that in chronic pain opioids have limited evidence for long-term efficacy
- the International Association for the Study of Pain (IASP) statement - "*There may be a role for medium-term, low-dose opioid therapy in carefully selected patients with chronic pain who can be managed in a monitored setting. However, with continuous longer term use, tolerance, dependence and other adaptations compromise both efficacy and safety*"
- the Faculty of Pain Medicine UK practice points:
  - *Patients who do not achieve useful pain relief from opioids within two to four weeks are unlikely to gain benefit in the long term.*
  - *Patients who may benefit from opioids in the long term will demonstrate a favourable response within two to four weeks.*
  - *Short-term efficacy does not guarantee long-term efficacy.*
  - *Data regarding improvement in quality of life with long-term opioid use are inconclusive.*
    There is no good evidence of dose-response with opioids, beyond doses used in clinical trials, usually up to 120mg/day morphine equivalent. There is no evidence for efficacy of high dose opioids in long-term pain.
- tapentadol:
  - is a strong opioid that not only acts on the opioid receptor but also acts on noradrenergic reuptake inhibition
  - is not a pro-drug, and its side effects are reflective of opioids rather than noradrenergic reuptake inhibitors
  - [unlike other opioids] has data for follow-up beyond 12 weeks
  - [unlike other opioids] has a maximum recommended dose (500mg twice daily)
  - will be used in line with the SMC recommendation (when morphine is not tolerated or contraindicated)
  - has a potential for abuse and addiction. Currently the abuse prevalence is low but this may be due to low prescribing of tapentadol.
  - is not licensed for children and adolescents
- there is a possible gap in 'as required' medication if only the prolonged-release preparation is available. In addition, prescribers may prefer to have one single molecule for use in acute and chronic pain, so the request includes standard-release and prolonged-release tablets.
- morphine is a more established/familiar drug. It is included on the Scottish Drug Tariff

(SDT) and is more cost-effective.
- when/if prescribing opioids:
  - prescribers must have a clear indication for prescribing
  - if there is no efficacy beyond two weeks of the titration phase, then prescribing should be withdrawn
  - prescribing should be reviewed on a regular basis, at least annually. Review for efficacy and side-effect profile; including endocrine effects (particularly gonadotrophic effects with high doses of opioids).
- locally the dosage of tapentadol does not go beyond 300mg/daily [~ 120mg morphine equivalent]

It was confirmed that:
- the introduction of tapentadol would affect the prescribing of oxycodone (tapentadol would be considered for patients where you would otherwise consider oxycodone)
- locally there is some use of both immediate-release and prolonged-release tapentadol
- other Health Boards have included the prolonged-release preparation on their formularies, none have included the standard-release preparation

The Group noted that:
- people respond differently to different drugs
- patients with chronic pain may have significant psychological overlay
- pharmacological treatments are not the only options for the management of non-malignant pain
- there is limited access to specialists at the pain clinic

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

8.1 SMC 654/10 – TAPENTADOL PROLONGED-RELEASE (SEVERE CHRONIC PAIN)

Mrs Harper declared a non-specific, non-personal interest in Grunenthal Ltd and took part in decision-making.

A member noted that in his submission Dr Kanakarajan declared a personal specific interest for this medicine [from 2017].

It was confirmed that:
- at list price, the cost of tapentadol is on a par with oxycodone, however confidential pricing arrangements may be in place for some oxycodone products
- the Grampian Area Drug and Therapeutics Committee (GADTC) is linking with the specialist service to promote quality improvement in prescribing for adults with chronic pain
- tapentadol is due to come off patent in 2021
- tapentadol immediate-release tablets are not recommended by SMC, based on a non-submission by the Marketing Authorisation Holder (MAH)

The Group agreed that:
- tapentadol is a strong opioid and as Primary Care Clinicians already prescribe strong opioids, restricting prescribing to 'only on the advice of pain consultants' would not be reasonable
- all opioids have the potential for harm and the addiction potential of tapentadol may not be fully elucidated
- the use of opioids in chronic pain should be a considered choice

The Group did not support formulary inclusion of immediate-release tapentadol noting that SIGN 136 advises - "*Aim to establish the patient on a long-acting opioid with no*

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immediate release opioid if the chronic pain is stable. For mild breakthrough pain' consider non-opioids (e.g. paracetamol, NSAIDs); a weak opioid."

The Group discussed the request at length and supported the prescribing of tapentadol prolonged-release only within the context of an NHS Grampian chronic pain management pathway with guidance from the pain clinic as to:

- which patients should be considered for opioids
- when to start opioids, including dose titration
- how to deescalate doses of opioids
- how to switch to or from tapentadol/other opioids

The Group accepted the restricted local need for tapentadol prolonged-release tablets for the management of severe chronic non-malignant pain in adults. Prescribing is restricted in line with SMC 654/10.

SMC 654/10 - Tapentadol prolonged-release (Palexia® SR) is routinely available in line with national guidance (SMC 654/10).
Indication under review: the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.
Restriction: adults in whom morphine sulphate modified-release has failed to provide adequate pain control or is not tolerated.
Results of a meta-analysis of three, 12-week studies suggest that tapentadol prolonged release has improved gastrointestinal tolerability and similar efficacy compared to another long-acting opioid included as an active control.
It was classified 1a - available for general use and 8e - treatment may be initiated in either Primary or Secondary care.
SMC has not yet received a submission for tapentadol immediate release tablets for the relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics. Tapentadol immediate release tablets are not recommended for use in NHS Scotland. **FTeam**

3.2. CAR-T CELL THERAPY

Dr Gavin Preston, Consultant Haematologist, provided the Group with a comprehensive review of the development, current and future use of Chimeric Antigen Receptors T-Cell (CAR-T) therapies.

The Chairman thanked Dr Preston for attending the meeting and providing the Group with a very informative presentation.

4. MATTERS ARISING

4.1. ACTION LOG

No items were identified that were not included on the agenda.

4.2. MOVIPREP® (UPDATE)

Ms Doney reported that the introduction of Moviprep® is on hold as the Head of Service is reviewing the local bowel preparation guidelines. **PP**

4.3. CAPHOSOL® (FORMULARY STATUS UPDATE)

Caphosol® supersaturated calcium phosphate rinse is currently included on the formulary for specific patient groups, e.g. patients undergoing radiotherapy for head and neck cancer.

At the September meeting, the Group discussed the discrepancy between the North Cancer Alliance (NCA) guideline for the prevention and treatment of oral mucositis and

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the local formulary status. The Group supported no change to formulary status pending clarification of the local and regional treatment preferences.

Ms Galvin confirmed that following discussion with colleagues in NHS Grampian Caphosol® mouthwash should be recorded as non-formulary. Additionally, there is currently no desire to consider Caphosol® tablets for inclusion on the formulary, if the situation changes a submission will be progressed. **MG**

The formulary website and ScriptSwitch profile will be updated noting Caphosol® as non-formulary. **FTeam/AD**

Caphosol® supersaturated calcium phosphate rinse is not routinely available as there is a local preference for alternative medicines.
Indication under review: for the prevention of oral mucositis in patients undergoing radiotherapy for head and neck cancer, and restricted use for patients undergoing chemotherapy.
Not routinely available as there is a local preference for alternative medicines. **FTeam**

5. FORMULARY GROUP DECISIONS SEPTEMBER 2019 – PUBLISHED – 02/10/2019

Members ratified the decisions of the September 2019 meeting as published.

6. NETFORMULARY/FORMULARY REVIEW

6.1. ENZALUTAMIDE

Ms Doney reported that the formulation of enzalutamide is changing from capsules to tablets. The Formulary Team is waiting for confirmation that the current PAS applies to the new formulation. There is an additional strength noted on the new Summary of Product Characteristics (SmPC), however it appears that the MAH is not marketing this product in the UK.
The Formulary Team will maintain a watching brief on this item. **FTeam**

6.2. ERENUMAB

Ms Doney reported that a higher strength [140mg] of erenumab is now available, the PAS applies to the new strength and the formulary entry has been updated.

6.3. SECUKINUMAB

Ms Doney reported that the SmPC for secukinumab now includes dosing flexibility for patients with ankylosing spondylitis (AS) or psoriatic arthritis (PsA) [for patients with active disease secukinumab now has approval for up-titration to 300mg, previous recommended dose was 150mg]. The medicine cost will potentially double and this change in maximum dose is outwith remit for SMC.

The SMC assessment for PsA included assessment of the 300mg dose, and the higher dose was considered cost-effective. There is no cost-effectiveness analysis for the 300mg dose in AS patients, however the relative costs against the range of comparators is available.

Dr MacDonald confirmed that PsA patients were likely to be getting the 300mg dose [due to their concurrent psoriasis] and the impact from AS patients is unlikely to be significant.

6.4. FORMULARY WORK PROGRAMME

Ms Doney apologised that the formulary work programme was not available for the meeting.

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7. OTHER BUSINESS

7.1. EUROPEAN ANTIBIOTIC AWARENESS DAY/WEEK (18 NOVEMBER 2019)

This item was noted.

7.2. NHS GRAMPIAN: UK GENERAL ELECTION 2019 – ELECTION GUIDANCE

Ms Doney confirmed that during the NHS pre-election period it is 'business as usual' for the Formulary Group, i.e. the November formulary decisions will be published by 3 December.

7.3. CALL FOR VIEWS SCOTTISH GOVERNMENT HEALTH AND SPORT COMMITTEE

The Group noted that the Scottish Government Health and Sport Committee is seeking views on the management of the medicines budget, including the clinical and cost-effectiveness of prescribing.

Ms Doney confirmed that this item was discussed at the November meeting of the Grampian Area Drug and Therapeutics Committee (GADTC), and the Chairman of the committee is taking forward a response.

The Group was unclear of the objectives of the Health and Sport Committee's call for views and felt that the questions seemed at odds with the exclusions.

The Chairman confirmed that the consultation was open to everyone and the closing date is the 22 November 2019.

7.4. PRAC MEETING HIGHLIGHTS OCTOBER 2019

Ms Doney confirmed that the formulary entries for alemtuzumab and tofacitinib have been updated and the Pharmacovigilance Risk Assessment Committee (PRAC) recommendations have been shared with the specialist services.

7.5. GLIBENCLAMIDE 2.5MG AND 5MG TABLETS

The Group noted that glibenclamide 2.5mg and 5mg tablets have been discontinued by Wockhardt and there are no other manufacturers in the market. The withdrawal will be highlighted on the formulary. **FTeam**

7.6. VALGANCICLOVIR (UPDATE)

Ms Doney reported that discussions at a national level are ongoing. If there is no movement on this issue the potential for a change in the supply route for valganciclovir will be discussed at a future meeting. **FTeam**

8. NEW PRODUCT REQUESTS

Items 8.2 to 8.5 were taken together.

8.2. FG1SMC 2135 – ABEMACICLIB ((HER2) BREAST CANCER IN COMBINATION WITH AN AROMATASE INHIBITOR)

8.3. FG1SMC 2179 – ABEMACICLIB ((HER2) BREAST CANCER IN COMBINATION WITH FULVESTRANT)

8.4. FG1SMC 2149 – PALBOCICLIB ((HER2) BREAST CANCER IN COMBINATION WITH FULVESTRANT IN WOMEN WHO HAVE RECEIVED PRIOR ENDOCRINE THERAPY)

8.5. FG1SMC 2198 – RIBOCICLIB (HER2) BREAST CANCER IN COMBINATION WITH FULVESTRANT

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Mrs Harper declared a non-specific, non-personal interest in Pfizer, and took part in decision-making.
Mrs Harper and Ms Galvin declared non-specific, non-personal interests in Novartis, and both took part in decision-making.

The Group discussed the submissions for the cyclin-dependent kinase inhibitors [CDK 4/6 inhibitors], abemaciclib and palbociclib.

The Group noted that:

- there are two indications considered in the requests. Abemaciclib used in combination with an aromatase inhibitor and, abemaciclib or palbociclib used in combination with fulvestrant.
- [within the relevant indication] the products will compete with each other, and the service has completed separate submissions only because of the timing of licensing and restrictions in the SMC advice
- introduction of these agents will improve progression-free survival (PFS) for these patient groups
- use [of CDK 4/6 inhibitors] in combination with fulvestrant is a new line of therapy with no offset, whereas both palbociclib and ribociclib are already included on the formulary when used in combination with an aromatase inhibitor
- ribociclib has more monitoring requirements than the other CDK 4/6 inhibitors [ECG monitoring] and may not be a preferred option locally
- if patients fail on a CDK 4/6 inhibitor in combination with an aromatase inhibitor, patients will not be switched to another CDK 4/6 inhibitor or stay on the current CDK 4/6 inhibitor and add in fulvestrant
- moving forward patients will get these agents first-line however there will be a cohort of patients on adjuvant aromatase inhibitor (for up to 10 years) who on progression would be eligible for a CDK 4/6 inhibitor plus fulvestrant

The Group accepted the restricted local need for abemaciclib in combination with an aromatase inhibitor, as outlined in SMC 2135.

SMC 2135 - Abemaciclib 50mg, 100mg, 150mg tablets (Verzenios®) ▼ is routinely available in line with national guidance (SMC 2135).
Indication under review: for the treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor* as initial endocrine-based therapy, or in women who have received prior endocrine therapy.
In a phase III randomised study in women with HR-positive, HER2-negative advanced breast cancer, abemaciclib in combination with an aromatase inhibitor significantly increased progression-free survival compared with aromatase inhibitor monotherapy.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of abemaciclib and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
***For SMC advice relating to the use of abemaciclib in combination with fulvestrant in this setting, please refer to SMC 2179. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Therapy should be initiated and supervised by physicians experienced in the use of anti-cancer therapies.**

FTeam

The Group accepted the restricted local need for abemaciclib in combination with fulvestrant, as outlined in SMC 2179.

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	SMC 2179 - Abemaciclib 50mg, 100mg, 150mg tablets (Verzenios®)▼ is routinely available in line with national guidance (SMC 2179). **Indication under review: for the treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with fulvestrant* as initial endocrine-based therapy or in women who have received prior endocrine therapy.** **Restriction: for use in women who have progressed on or after (neo) adjuvant endocrine therapy, or progressed during first-line endocrine-based therapy for advanced breast cancer** **In a phase III randomised study in women with HR-positive, HER2-negative advanced breast cancer who had received prior endocrine therapy, abemaciclib in combination with fulvestrant significantly increased progression-free survival compared with endocrine monotherapy.** **This advice takes account of the benefit of Patient Access Schemes (PAS) that improve the cost effectiveness of abemaciclib and fulvestrant and is contingent upon the continuing availability of these PAS in NHS Scotland or list prices that are equivalent or lower.** **This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.** *** For SMC advice relating to the use of abemaciclib in combination with an aromatase inhibitor in this setting, please refer to SMC 2135. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Therapy should be initiated and supervised by physicians experienced in the use of anti-cancer therapies.**	**FTeam**
	The Group accepted the restricted local need for palbociclib in combination with fulvestrant, as outlined in SMC 2149.	
	SMC 2149 - Palbociclib 75mg, 100mg, 125mg hard capsules (Ibrance®)▼ is routinely available in line with national guidance (SMC 2149). **Indication under review: for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer:** **- in combination with an aromatase inhibitor;** **- in combination with fulvestrant in women who have received prior endocrine therapy.** **In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.** **This submission relates to use in combination with fulvestrant in women who have received prior endocrine therapy.** **In a phase III study palbociclib plus fulvestrant, compared with fulvestrant, prolonged progression-free survival in women with HR-positive HER2-negative locally advanced or metastatic breast cancer who had received prior endocrine therapy.** **This advice takes account of the benefits of Patient Access Schemes (PAS) that improve the cost-effectiveness of palbociclib and fulvestrant and is contingent upon the continuing availability of these PAS in NHS Scotland or list prices that are equivalent or lower. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.**	**FTeam**
	Due to its increased monitoring requirements [ECG monitoring] local clinical experts do not wish to add ribociclib [in combination with fulvestrant] to the formulary at this time.	
	SMC 2198 - Ribociclib 200mg film-coated tablets (Kisqali®)▼ is not routinely available as local clinical experts do not wish to add the medicine to the formulary	

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at this time.
Indication under review: for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with fulvestrant* as initial endocrine-based therapy, or in women who have received prior endocrine therapy.
Restriction: women who have relapsed on or within 12 months of completing (neo) adjuvant endocrine therapy, or those who have progressed on first-line endocrine-based therapy for advanced breast cancer.
Ribociclib in combination with fulvestrant significantly increased progression-free survival compared with endocrine monotherapy in women with HR-positive, HER2-negative locally advanced or metastatic breast cancer.
This advice takes account of the benefit of Patient Access Schemes (PAS) that improve the cost effectiveness of ribociclib and fulvestrant and is contingent upon the continuing availability of these PAS in NHS Scotland or list prices that are equivalent or lower.
This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.
Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time. **FTeam**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED NOVEMBER 2019

The Group noted the SMC provisional advice issued November 2019.

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 OCTOBER AND NOVEMBER 2019

SMC ADVICE PUBLISHED OCTOBER 2019

The Group noted the SMC advice published October 2019.

Following publication of the negative SMC recommendations, for enzalutamide (Xtandi®) ▼ SMC 2195 and pertuzumab (Perjeta®) SMC 2197, and the non-submission statements, for eculizumab (Soliris®) SMC 2236 and glibenclamide (Amglidia®) SMC 2237, these medicines will not be included on the Grampian Joint Formulary for the indications in question.

It was reported that glibenclamide oral suspension, as Amglidia®, is licensed to treat newborns and children with neonatal diabetes, and in patients with whose diabetes is caused by certain genetic mutations.
Ms Doney confirmed that Amglidia® is not recommended for use in NHS Scotland, due to non-submission by the manufacturer. It is available as 30mL bottles; 600micrograms/mL oral suspension £2,100.00 (ex VAT), and the 6mg/mL oral suspension £21,000.00 (ex VAT).

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

- SMC 2207 pembrolizumab (Keytruda®) ▼ (submission expected)
- SMC 2196 risankizumab (Skyrizi®) ▼ (submission expected)
- SMC 2186 triptorelin (Decapeptyl SR®)

Local advice for these medicines and indications will be included in the November 2019 decisions as 'Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.' **FTeam**

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SMC 2189 AXICABTAGENE CILOLEUCEL (LARGE B CELL LYMPHOMA)

The Group accepted that axicabtagene would be recorded as non-formulary, routinely available from a specialist centre in another health board.

SMC 2189 - Axicabtagene ciloleucel 0.4 – 2 x 10^8 cells dispersion for infusion (Yescarta®) ▼ is routinely available from a specialist centre in another health board.
Indication under review: treatment of adult patients with relapsed or refractory diffuse large B cell lymphoma (DLBCL) and primary mediastinal large B cell lymphoma (PMBCL), after two or more lines of systemic therapy.
Axicabtagene ciloleucel was associated with an objective response rate of 82% in a single-arm, open-label, phase I/II study in patients with refractory DLBCL.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of axicabtagene ciloleucel 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.
Routinely available from a specialist centre in another health board. **FTeam**

SMC ADVICE PUBLISHED NOVEMBER 2019

The Group noted the SMC advice published November 2019.

Following publication of the negative SMC recommendation, for atezolizumab (Tecentriq®) ▼ SMC 2208, and the non-submission statements, for ibrutinib (Imbruvica®) SMC 2244, ibrutinib (Imbruvica®) SMC 2245 and ramucirumab (Cyramza®) SMC 2246, 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 2194 pentosan polysulfate sodium (Elmiron®)
- SMC 2212 clostridium botulinum neurotoxin type A (Xeomin®) (submission expected)
- SMC 2222 trientine tetrahydrochloride (Cuprior®) (submission expected)
- SMC 2199 lenvatinib (Kisplyx®) ▼
- SMC 2211 imiquimod (Zyclara®)

Local advice for these medicines and indications will be included in the November 2019 decisions as 'Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts.' **FTeam**

SMC 2214 MAVIRET® (CHRONIC HEPATITIS C VIRUS – ADOLESCENTS)

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

The Group noted:

- Maviret®:
  - is a fixed-dose combination tablet (glecaprevir/pibrentasvir) licensed for the treatment of chronic hepatitis C
  - is already included on the formulary for the treatment of chronic hepatitis C virus (HCV) infection in adults
- this abbreviated SMC advice extends the use of Maviret®, for the treatment of chronic HCV infection to include adolescents aged 12 to <18 years
- treatment of adolescents with HCV will be directed by local specialists

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- currently there are no patients requiring treatment, however if a local need was identified inclusion on formulary would facilitate access to treatment.

The Group accepted the restricted local need for Maviret® 100mg/40mg film-coated tablets for the treatment of chronic HCV infection in adolescents aged 12 to <18 years without the need for a submission.

SMC 2214 - Maviret® 100mg/40mg film-coated tablets (glecaprevir/pibrentasvir) is routinely available in line with national guidance (SMC 2214).
Indication under review: treatment of chronic hepatitis C virus (HCV) infection in adolescents aged 12 to <18 years.
SMC has previously accepted glecaprevir/pibrentasvir for the treatment of chronic HCV infection in adults.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of glecaprevir/pibrentasvir and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and monitored by a physician experienced in the management of patients with HCV infection. **FTeam**

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.

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM – NOVEMBER 2019

ATEZOLIZUMAB (TECENTRIQ) SMC 1336/18

Ms Doney reported that atezolizumab is now available in a new strength vial, 840mg concentrate for infusion. The new strength will not be assessed by SMC but the PAS has been updated to include new 840mg vial. The new strength provides a 6-week dose regimen.

The product will be assessed locally, with information coming to a future meeting. **FD/MG**

CHANGES TO STREAMLINE THE SMC SUBMISSION PROCESSES

The Group noted the information from the SMC outlining changes to process that will be introduced.

- New formulations that cost the same or less than established medicines
  From October 2019, companies have been advised that new strengths, new formulations or new presentations of medicines that cost the same or less than the established product(s), where these have been accepted for use in the same indication by SMC/HIS (or which became available before 2002), will be considered outwith remit. This includes new devices for the administration/delivery of established proprietary medicines.
  New formulations that cost more than the established medicine will continue to require assessment via the abbreviated or full submission process.

- Paediatric licence extensions
  From January 2020, companies will be advised that abbreviated submissions will no longer be requested. SMC will update ADTCs when paediatric licence extensions are granted and highlight SMC advice for the corresponding indication in adults, however no SMC advice statement will be issued. PASAG will update Boards on the extension of a PAS (where relevant) to include the younger age group.
  Boards have the opportunity to contact SMC if they feel an assessment of a particular

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paediatric licence extension would be of value.

- SMC resubmissions process
  From January 2020, companies will be advised that a resubmission made within three months of the original SMC decision may proceed via a fast-track process where the only change relates to a new or improved PAS. This will allow the resubmission to proceed directly to SMC with no consideration by NDC.

12. DOCUMENTS FOR INFORMATION

ITEMS 12.1 (MHRA DRUG SAFETY UPDATE SEPTEMBER 2019)
The Chairman highlighted the September Drug Safety Update article regarding montelukast and the risk of neuropsychiatry reactions.

Items 12.2 (MHRA Drug Safety Update October 2019), 12.3 (MEDWatch October 2019), 12.4 (AMT minute July 2019), 12.5 (AMT minute August 2019) and 12.6 (Formulary Group Meeting Dates 2020) were noted.

13. AOCB - NONE

DATE OF NEXT MEETING

Tuesday 17 December 2019 starting at 14:30 in the Seminar Room, David Anderson Building.

CHAIRMAN'S SIGNATURE **DATE** **21 January 2020**