TAM SUBGROUP OF THE NHS HIGHLAND AREA DRUG AND THERAPEUTICS COMMITTEE

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MINUTE of meeting of the TAM Subgroup of NHS Highland ADTC
8 December 2022, via Microsoft TEAMS

Present:	Alasdair Lawton, Chair Patricia Hannam, Formulary Pharmacist Findlay Hickey, Principal Pharmacist (Medicines Management and Prescribing Advice) Dr Duncan Scott, Consultant Physician Dr Jude Watmough, GP Jenny Munro, AP Physiotherapist, Continence and Independent Prescriber Damon Horn, HEPMA Pharmacist Joanne McCoy, LGOWIT Manager Dr Antonia Reed, GP Dr Robert Peel, Consultant Nephrologist Joan Mackintosh, Clinical Pharmacist Team Manager Dr Alan Miles, GP Louise Reid, Acute Pain Nurse Lead/Claire Wright, Acute Pain Nurse Linda Burgin, Patient Representative Simon Thompson, Consultant Physician
In attendance:	Wendy Anderson, Formulary Assistant Donna Fraser, TAM Project Support Manager John MacGillivray, Primary Care Pharmacist Lorna Murray (item 10.8) Susan Caldwell (item 16)
Apologies:	No apologies received

1. WELCOME AND APOLOGIES

The Chair welcomed the group.

2. REGISTER OF INTEREST

No interests were declared.

3. MINUTES OF MEETING HELD ON 27 October 2022

Accepted as accurate.

4. FOLLOW UP REPORT

Noted.

5. SUBMISSIONS FOR ADDITION TO HIGHLAND FORMULARY FOR APPROVAL

5.1. SBAR: Chemotherapy submission process

This SBAR was written to streamline the submission process for SMC approved medications for oncology and haematology for the treatment of cancer. There is a backlog of submissions and both the oncology and haematology teams are stretched at Raigmore Hospital to the point that these is risk of impact to patient care. Scottish Government does demand that for cancer medications there is a place in therapy stated and that treatment pathways are in place prior to use. This submission process to the Subgroup would be under the caveats that these requirements are upheld and that any finance and/or resource implications would be identified and addressed within the department and that any medicines that are requested to be used out with the SMC recommendation would follow the standard formulary submission process.

The SBAR was presented to ADTC who were supported of this process.
The following points were noted:

- Ensure that we are not missing any capture of data that isn't going to be captured elsewhere in the organisation.
- Environmental impact should be provided. An EMA check to be done for each submission.
- This puts a different responsibility on those using the medicines to ensure that they have the pathways and protocols for the use of the medicines all in place. This is a requirement that has to be fulfilled.
- This is an interim process. As discussed at past meetings it had been expected that the North Cancer Alliance would take on the governance of these medicines It was hoped that development of a centralised process looking at the north of Scotland health boards would be put in place to assess these medicines and put them within a pathway and disseminate to the health board.

The SBAR and interim process was agreed.

5.2. Haematology Chemotherapy formulary submissions

All accepted.

Asciminib 20mg and 40mg film-coated tablets (Scemblix) Novartis Pharmaceuticals UK Ltd	SMC2482 07/10/22 Full submission under the orphan equivalent medicine process
Daratumumab 1,800mg solution for injection (Darzalex) Janssen-Cilag Ltd	SMC2447 08/07/22 Full submission under the orphan medicine process. Accepted for use.
Fedratinib 100mg hard capsules (Inrebic) Bristol-Myers Squibb Pharmaceuticals Ltd	SMC2462 04/03/22 Abbreviated submission. Accepted for use.
Gilteritinib 40mg film-coated tablets (Xospata) Astellas Pharma Ltd	SMC2252 07/08/20 Full submission. Accepted for use.
Hydroxycarbamide 100mg/mL oral solution (Xromi) Nova Laboratories Ltd	SMC2271 10/07/20 Abbreviated submission. Accepted for restricted use.
Zanubrutinib 80mg hard capsules (Brukinsa) BeiGene UK Ltd	SMC2528 07/10/22 Resubmission under the orphan equivalent medicine process. Accepted for use.

5.3. Oncology Chemotherapy formulary submissions

Atezolizumab 1,200mg concentrate for solution for infusion (Tecentriq) Roche Products Ltd	SMC2349 04/06/21 Full submission under the end of life process. Accepted for use.
Atezolizumab 840mg and 1,200mg concentrate for solution for infusion (Tecentriq) Roche Products Ltd	SMC2379 08/10/21 Full submission. Accepted for use. SMC2492 08/07/22 Full submission. Accepted for use.
Brigatinib 30mg, 90mg and 180mg film-coated tablets (Alunbrig) Takeda UK Ltd	SMC2314 04/12/20 Abbreviated submission. Accepted for use.
Dostarlimab 500mg concentrate for solution for infusion (Jemperli) GlaxoSmithKline	SMC2404 10/12/21 Full submission. Accepted for use on an interim basis subject to ongoing evaluation and future reassessment.
Encorafenib 50mg and 75mg hard capsules	SMC2312

(Braftovi) Pierre Fabre Ltd	09/04/21 Full submission under end of life and orphan equivalent process. Accepted for use.
Entrectinib 100mg and 200mg hard capsules (Rozlytrek) Roche Products Ltd	SMC2294 04/12/20 Full submission under the orphan equivalent process. Accepted for use. SMC2295 05/02/21 Full submission under the end of life and orphan equivalent process. Accepted for use.
Lorlatinib 25mg and 100mg film-coated tablets (Lorviqua) Pfizer Ltd	SMC2415 04/02/22 Abbreviated submission. Accepted for use.
Niraparib 100mg hard capsules (Zejula) GlaxoSmithKline UK	SMC2338 09/04/21 Full submission under end of life and orphan medicine process. Accepted for use.
Nivolumab 10mg/mL concentrate for solution for infusion (Opdivo) Bristol-Myers Squibb Pharmaceuticals Ltd	SMC2429 08/04/22 Full submission. Accepted for use. SMC2385 14/01/22 Full submission under end of life process. Accepted for use. SMC2394 05/11/21 Full submission. Accepted for use.
Olaparib 100mg and 150mg film-coated tablets (Lynparza) AstraZeneca UK Ltd	SMC2367 09/07/21 Abbreviated submission. Accepted for restricted use. SMC2368 Full submission under the orphan equivalent medicine process. Accepted for use.
Pembrolizumab 25mg/mL concentrate for solution for infusion (Keytruda) Merck Sharp & Dohme (UK) Ltd	SMC2375 06/08/21 Full submission. Accepted for restricted use. SMC2420 08/04/22 Full submission under the end of life medicine process. Accepted for restricted use.
Pemigatinib 4.5mg, 9mg, and 13.5mg tablets (Pemazyre) Incyte Biosciences UK Ltd	SMC2399 14/01/22 Full submission under end of life and orphan process. Accepted for use.
Selpercatinib 40mg and 80mg hard capsules (Retsevmo) Eli Lilly and Company Ltd	SMC2370 06/08/21 Full submission assessed under the end of life and orphan equivalent process. Accepted for use on an interim basis subject to ongoing evaluation and future reassessment.
Sotorasib 120mg film-coated tablets (Lumykras) Amgen Ltd	SMC2443 04/02/22 Full submission assessed under the end of life and orphan equivalent process. Accepted for use on an interim basis subject to ongoing evaluation and future reassessment.
Trametinib 0.5mg, 2mg film-coated tablets (Mekinist) Novartis Pharmaceuticals UK Ltd	SMC2328 05/02/21 Abbreviated submission. Accepted for restricted use.
Trifluridine-tipiracil 15mg/6.14mg and 20mg/8.19mg film-coated tablets (Lonsurf) Servier Laboratories Ltd	SMC2329 07/05/21 Full submission assessed under the orphan equivalent and end of life process. Accepted for restricted use.

5.4. Silver diamine fluoride
Submitted by: John Lyon, Director of Dentistry

Indication: Dental Caries prevention/arrest dental caries.
Comments: Off-licence use of a licensed medical device. A guideline to go alongside this preparation has been submitted.
ACCEPTED

5.5. Bempedoic acid (Nilemdo) 180mg film-coated tablets (SMC2363)
Submitted by: Rosemary Clarke, Consultant Medical Biochemist
Indication: In adults with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- In combination with a statin, or a statin with other lipid-lowering therapies in patients unable to reach low-density lipoprotein cholesterol (LDL-C) goals with the maximum tolerated dose of a statin or
- Alone or in combination with other lipid-lowering therapies in patients who are statin intolerant, or for whom a statin is contra-indicated.

SMC restriction: for use in combination with ezetimibe in patients who are:

- statin intolerant or for whom a statin is contra-indicated and
- where ezetimibe alone does not appropriately control LDL-C and
- where proprotein convertase subtilisin/kexin type 9 (PCSK9)

Comments: There is a compound cholesterol lowering product available that is SMC approved. If the compound medicine is more cost effective can it be used instead of the individual medicine? Noted that ezetimibe is already on the formulary.
ACCEPTED pending
Action
Post minute annotation: rejected in place of bempedoic acid/ezetimibe combo (Nustendi).

5.6. Real-time Continuous Glucose Monitoring (sensor only) (Dexcom One)
Submitted by: Dr David Macfarlane, Consultant Physician
Indication: Patients with Type 1 and Type 2 diabetes on multiple daily insulin injections (2 years+) and pregnant women.
Comments: This is a medical device. It will be the first continuous monitoring device in NHS Highland. Offers convenience to patients. Clarification required on place in therapy with relevant guidance to be updated. Mention of a free transmitter in the submission, more information to be provided as to what the process is for this, ie where does it come from and is procurement aware? Agreed that as more consumables are being prescribed, both Freestyle Libra and this formulation to be added to the Formulary.
ACCEPTED
Action

5.7. Faricimab (Vabysmo) 120mg/mL solution for injection (SMC2499)
Submitted by: Jane Wylie, Lead Pharmacist Surgery and Anaesthetics
Indication: For the treatment of adult patients with visual impairment due to diabetic macular oedema (DMO).
SMC restriction: treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) of 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline.
Comments: It is expected to be cost saving compared to current therapies, however there is a slight risk that it could be a cost pressure depending on the frequency of treatments given.
ACCEPTED

5.8. Faricimab (Vabysmo) 120mg/mL solution for injection (SMC2512)
Submitted by: Jane Wylie, Lead Pharmacist Surgery and Anaesthetics
Indication: For the treatment of adult patients with neovascular (wet) age-related macular degeneration (nAMD).
Comments: It is expected to be a cost saving compared to current therapies, however there is a slight risk that it could be a cost pressure depending on the frequency of treatments given.
ACCEPTED

5.9. Famotidine 20mg and 40mg tablets
Submitted by: Catriona Wheelan, Lead Pharmacist, Gastroenterology
Indication: As per SPC – duodenal and benign gastric ulcers which have been confirmed by radiological or endoscopic examination. Zollinger-Ellison syndrome. Reflux oesophagitis confirmed by endoscopy, including curative treatment of erosion or ulcer associated with reflux oesophagitis.
Comments: Ranitidine has been discontinued and currently there is no H2 antagonist on the Formulary. Famotidine is already being prescribed occasionally in Highland and should only be prescribed to patients that are intolerant to PPIs. Concern that the numbers quoted on the submission are very high. Very tight guidelines need to be put in place regarding prescribing, state limit use to where PPIs are unsuitable.

Request a strong place in therapy is put in place so that it is only used whereby PPIs cannot be tolerated. A Pink One article to be written to reinforce the strict prescribing criteria.

ACCEPTED pending

Action

6. FORMULARY MINOR ADDITIONS/DELETIONS/AMENDMENTS

Noted and approved pending one change – to be consistent, aztreonam to be changed to either use 4 times a day OR every 6 hours.

Action

7. FORMULARY REPORT

Noted.

8. SMC ADVICE

Noted.

9. NEW TAM GUIDANCE FOR APPROVAL

9.1. Adult IV Fluid Guideline

- Add a line at start of the document to say patients in high dependency areas and intensive care areas may need more tailored fluid prescribing.
- Guideline to be highlighted to Community hospitals and out of hours to raise awareness.

ACCEPTED pending

Action

9.2. Bronchiolitis

This was rejected at the last Subgroup, was sent back to the author for amendment based on comments received and has been published TAM.

ACCEPTED

9.3. Silver Diamine Fluoride

This is guidance to support the submission that was discussed and accepted earlier in the meeting. This is the first dental guideline for TAM and the Subgroup may be asked to approve other dental guidance.

ACCEPTED

9.4. Raigmore emergency ophthalmology admission protocol

- Introduction to be rewritten.

ACCEPTED pending

Action

10. GUIDELINE UPDATES

10.1. DMARD monitoring in Primary Care

This is guidance developed where all the different specialisms that use these medications agreed to having a standardised monitoring system so that GPs didn't have to have different way of monitoring patients. During COVID-19 the monitoring time frame was expanded so that patients didn't have to attend their GP so often. This is no longer relevant and so the guidance has been amended. Rather than reverting to the previous guidance, this guidance links to NICE guidance. This lists more medicines than what had originally been listed. Agreement had been received from a couple of the specialisms but not from all. Looking for feedback from the Subgroup to see if this link to national guidance is more appropriate than using localised guidance.

- Is there good evidence base for tightening monitoring back up again? This is more expensive in terms of spend on tests and use of primary care time, which is under a lot of strain. There doesn't seem to be any direction nationally for expanded monitoring. Request rheumatology or Medicine Information to take this forward, if they consider this to be appropriate.
- Highlight to GPs that if the drugs are being used for Dermatology that additional bloods need to be done. Dermatology need to do this in generic format as well as on a patient by patient situation.
- Provide information as to what tube should be used.

ACCEPTED pending

Action

10.2. Treatment of medically unwell patients with anorexia nervosa

This guidance used to be called MARZIPAN but is now called MEED (Medical Emergencies and Eating Disorders).

- Amend title to include what the abbreviation MEED stands for.
- These are presented as a number of separate guidelines. These have been combined into one guideline under the the Highland Eating Disorder service.
- On the flow chart, BMI criteria requires inclusion of < or = as appropriate.

ACCEPTED pending

Action

10.3. Subcutaneous methotrexate

- The levels quoted for the Full Blood Count differ from NICE, check if there is a reason for this.

ACCEPTED pending

Action

10.4. Acute Pain guidance

Subcutaneous opioids

- No comments made.

Subcutaneous opioid flowchart

- Box stating "Has more than one hour less elapsed since the last dose of opioid or pain score, less than four after 30 minutes of administration or less, less than 30 milligram of opioid in four hours administered." Relates to morphine and oxycodone, concern that 30 milligrams of oxycodone is a lot larger a dose than 30 milligrams of morphine. Needs to be clear which opioid it relates to and perhaps include morphine equivalent.
- Reference is made to using the drug Kardex, HEPMA inpatient prescription also to be included.
- Amendments to be made and submitted as minor amendments to the next Subgroup meeting.

Epidural analgesia

- No comments made.

ACCEPTED pending

Action

10.5. Acute pain management in adults with renal impairment

- Change paracetamol wording to remove the word consider and instead state: reduce dose for patients less than 50kg.

ACCEPTED pending

Action

10.6. Testosterone replacement in menopause

- This is a straight lift from the British Menopause society guideline.
- Query if this is for menopausal women? Clarify the appropriate terminology.

ACCEPTED pending

Action

10.7. Gentamicin prescription chart

ACCEPTED

10.8. Precision pathway for severe asthma - resubmission

This pathway had been submitted to the October meeting and was rejected. Lorna Murray was in attendance to answer any questions and provided background information. It had been developed in conjunction with the National Severe Asthma platform.

Noted that:

- There are lots of abbreviations in the document but unfortunately this cannot be adjusted specifically for NHS Highland and that the abbreviations are stated in full at the bottom of the guideline.
- NHS Highland provides all the services mentioned in the pathway so it is relevant.
- Astra Zeneca are hosting and facilitating the pathway but it has been led by Tom Farden from NHS Tayside but it has been developed by a multidisciplinary team.
- In response to question regarding training primary care staff on the pathway, Respiratory run a

presentation in the Echo sessions to primary care.

- Still concern that it is badged with a drug company name.
- From a respiratory perspective, they do interact with drug companies and generally interact through a group of drug companies rather than through single drug companies. LM will provide information on what this group is to PH to feedback to TAM Subgroup, along with why the pathway was worked on in conjunction with a specific drug company.
- A clarifying statement to be added to the top to help understanding of how it was developed and who was involved in producing it.
- Has a declaration of interest been completed for those involved in this pathway's development?
- The terms and conditions were still cause of concern. Patients have a right to see what protocol they've been treated according to, so the stipulation to not share with patients would not be legally enforceable because you're using something to treat patients. However, in the meantime was agreed to host on the intranet with link on TAM only.
- In general if industry sponsored/supported guidance is to be used in NHS Highland (even though they may not have developed the pathway themselves) there should be due diligence into how it is created so that guidelines that could be somewhat flawed or biased because of the source of funding that was used to develop them are not used.
- Can recommendations be put to national organisations eg SIGN to update guidance and a form of words added on TAM to say that it has been accepted in the interim with the drug company's influence but a recommendation has been made? By putting this back to a national group it would mitigate risk. DS to provide contact details for SIGN to PH.

ACCEPTED

Action

11. GUIDELINE MINOR AMENDMENTS

Noted and approved.

12. GUIDANCE FOR NOTING ONLY (REVIEWED AND NO CHANGES MADE)

No reviews to report.

13. TAM REPORT

A brief update was provided.

- It has been agreed that TAM will move to the Right Decision Service. It had been hoped that the move would take place this month, however this has been delayed. Transfer of information to RDS was due to take place in January and should to be completed by March.
- A large piece of work has been undertaken regarding broken links.
- A new guidance template is being used; all links on TAM are now presented down the right-hand side of the guidance rather than in the body of it and this helps us in being able to identify broken links.
- The flow chart creator pathway that is embedded within TAM is now being used. This will help with any glitches with broken links because it means we are not linking to media within TAM.
- Ongoing discussion with Argyll and Bute was taking place to establish whether or not they require a similar platform.
- Clinical development fellows have been secured on an annually recurring basis to support guideline development within TAM.

14. ENVIRONMENT

Meetings were taking place with realistic medicine and the sustainability Quality Improvement team. In January there will be an environment/sustainability project amnesty to be able to get all the different projects in NHS Highland onto one database, and that will include items such as inhalers. This will be discussed at a future meeting.

15. NHS WESTERN ISLES

NHS Western Isles is supporting NHS Highland develop a common pathway for the prescription of liraglutide and similar medicines for weight management.

16. ANY OTHER COMPETENT BUSINESS

Use of Penthrox in endoscopy

Penthrox has previously been approved by TAM Subgroup for use in procedures such as in Accident and Emergency but now expanding use into other areas. A project trial is to be undertake, should Penthrox be added to the Formulary as an off label indication during this time or left as a non-Formulary item until the results have been discovered as to whether it is of benefit to these additional areas?

Susan Caldwell provided background information about this item and to discuss what the Group think would be the best government approach for this project. Back in August, NHS Scotland issued a climate emergency and sustainability strategy for the next four years and one of the aims is to reduce the environmental impact of NHS Scotland. As usage of Entonox is reducing, the team have been looking at other alternatives that could be used in place of this; one of the ideas was to trial a project to use the methoxyflurane or penthrox. Will be trialled in endoscopy where it this can be controlled. Data is already been captured on how much Penthrox is required per patient. The project has been started in Raigmore but the team are keen to roll it out across NHS Highland. Noted that current practice regarding ventilation of the rooms is not safe.

Agreed that it does not need to be added to the Formulary until after the trial results. Governance needs to be put in place but it is not within the remit of this Subgroup and should be done by the relevant department. An overarching non formulary agreement should be put in place for the relevant departments which will be management via the Pharmacy department but made clear that it is for trial purposes.

17. DATE OF NEXT MEETING

Next meeting to take place on Thursday 16 February, 14:00-16:00 via TEAMS.

Actions agreed at TAM Subgroup meeting

Minute Ref	Meeting Date	Action Point	To be actioned by
Bempedoic acid (Nilemdo) 180mg film-coated tablets (SMC2363) *Back to minutes*	December 2022	If the compound medicine is more cost effective can it be used instead of the individual drug?	**PH**
Real-time Continuous Glucose Monitoring (sensor only) (Dexcom One) *Back to minutes*	December 2022	• Clarification required on place in therapy with relevant guidance to be updated. • Mention of a free transmitter in the submission, more information to be provided as to what the process is for this, ie where does it come from and is procurement aware? • Agreed that as more consumables are being prescribed, both Freestyle Libra and this formulation to be added to the Formulary.	**PH**
Famotidine 20mg and 40mg tablets *Back to minutes*	December 2022	• Request a strong place in therapy is put in place so that it is only used whereby PPIs cannot be tolerated. • A Pink One article to be written to reinforce the strict prescribing criteria.	**PH**
Formulary minor additions/ deletions/amendments *Back to minutes*	December 2022	Aztreonam to be changed to either use 4 times a day OR every 6 hours.	**PH**
Adult IV Fluid Guideline *Back to minutes*	December 2022	• Add a line at start of the document to say patients in high dependency areas and intensive care areas may need more tailored fluid prescribing. • Guideline to be highlighted to Community hospitals and out of hours to raise awareness.	**PH**
Raigmore emergency ophthalmology admission protocol *Back to minutes*	December 2022	Introduction to be rewritten.	**PH**

DMARD monitoring in Primary Care *Back to minutes*	December 2022	• Is there good evidence base for tightening monitoring back up again? It is obviously more expensive in terms of spend on tests and use of primary care time as well, which is quite a finite resource at the minute under a lot of strain. There doesn't seem to be any direction nationally for expanded monitoring. Request rheumatology takes this forward. • Highlight to GPs that if the drugs are being used for Dermatology that additional bloods need to be done. Dermatology need to do this generically as well as on a patient by patient situation. • Provide information as to what tube should be used.	**PH**
Treatment of medically unwell patients with anorexia nervosa *Back to minutes*	December 2022	• Amend title to include what the abbreviation MEED stands for. • On the flow chart, BMI criteria requires inclusion of < or = as appropriate.	**PH**
Subcutaneous methotrexate *Back to minutes*	December 2022	The levels quoted for the Full Blood Count differ from NICE, check if there is a reason for this.	**PH**
Acute Pain guidance – Subcutaneous opioid flowchart *Back to minutes*	December 2022	• Box stating "Has more than one hour less elapsed since the last dose of opioid or pain score, less than four after 30 minutes of administration or less, less than 30 milligram of opioid in four hours administered." Relates to morphine and oxycodone, concern that 30 milligrams of oxycodone is a lot larger a dose than 30 milligrams of morphine. Needs to be clear which opioid it relates to and perhaps include morphine equivalent. • Reference is made to using the drug Kardex, HEPMA inpatient prescription also to be included. • Amendments to be made and submitted as minor amendments to the next Subgroup meeting.	**PH**
Acute pain management in adults with renal impairment *Back to minutes*	December 2022	Change paracetamol wording to remove the word consider and state: reduce dose for patients less than 50kg.	**PH**
Testosterone replacement in menopause *Back to minutes*	December 2022	Query if this is for menopausal women? Clarify the appropriate terminology.	**PH**
Precision pathway for severe asthma *Back to minutes*	December 2022	• From a respiratory perspective, they do interact with drug companies and generally interact through a group of drug companies rather than through single drug companies. LM will provide information on what this group is to PH to feedback to TAM Subgroup, along with why the pathway was worked on in conjunction with a specific drug company. • A clarifying statement to be added to the top to help understanding of how it was developed and who was involved in producing it. • Has a declaration of interest been completed	**PH/LM/DS**

		for those involved in this pathway's development? • Can recommendations be put to national organisations eg SIGN to update guidance and a form of words added on TAM to say that it has been accepted in the interim with the drug company's influence but a recommendation has been made? By putting this back to a national group it would mitigate risk. DS to provide contact details for SIGN to PH.	