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
31 October 2024, via Microsoft TEAMS

Present:	Alasdair Lawton, Chair Patricia Hannam, Professional Secretary, Formulary Pharmacist Findlay Hickey, Principal Pharmacist (Medicines Management and Prescribing Advice) Dr Robert Peel, Consultant Nephrologist Wendy Laing, Primary Care Clinical Pharmacist Lauren Stevenson, Pharmacist, Medicines Information Service Dr Jude Watmough, GP Joanne McCoy, MySelf-Management Manager Dr Simon Thompson, Consultant Physician Dr Antonia Reid, GP Dr Sarah Donald, GP Emma King-Venables, Lead AHP, A&B
In attendance:	Wendy Anderson, Formulary Assistant Claire Fortey, TAM Project Support Manager Dianne Ross, Renal Clinical Educator
Apologies:	Dr Stephen McCabe, Clinical Director, Primary Care (comments provided) Louise Reid, Acute Pain Nurse Specialist Claire Wright, Acute Pain Nurse Specialist Linda Burgin, Patient Representative

1. WELCOME AND APOLOGIES

The Chair welcomed the group.

2. REGISTER OF INTEREST

Nothing declared.

3. MINUTES OF MEETING HELD ON 29 AUGUST 2024

Minutes accepted as accurate.

4. ACTIONS FROM PREVIOUS MEETING

ITEM	ACTION POINT	ACTION	STATUS	COMMENTS
TAM656 Endometriosis	Agreed on TAM to consider listing the differences between the national guidance and NHS Highland services on the page that links to the guidance.	**PH**	In progress	Awaiting response from author
	Can a tighter flow chart/referral process be developed linking to the guidance as background information?		In progress	Awaiting response from author
	What information do the gynaecology team at Raigmore require?		In progress	Awaiting response from author
	Ask for an immediate comment that can be put on it to say that this will be further refined, as it's acknowledged that there's bits that don't align. Guidance then to be worked on and submitted as an amendment at a future subgroup.		Complete	

TAM647 Post-fall medication review	Cross link to relevant anticholinergic advice within the Polypharmacy guidance.	**PH**	Complete	
	Can slight changes be made as minor amendments after publication of this version, so that the document encompasses both secondary and primary care?		In progress	Awaiting response from author
COVID121 Drug management of adult hospital in-patients with COVID-19 infection following LFT/PCR positive	IDL and GP information re 3 month effect of tocilizumab on immune response to be reinstated.	**PH**	Complete	
	What is the definition of severe pneumonitis if patient is not on oxygen?	**PH**	In progress	Awaiting response from author
	The flow charts are not clear eg downward arrow in the flow chart makes the medicine prescribing confusing. PH to liaise with ST.	**PH/ST**	In progress	Awaiting response from author
	Amend 'pharmacy supply' to 'hospital pharmacy supply'.	**PH**	Complete	
COVID123 Risk factors for progression to severe COVID-19 infection	When you have identified a patient what is the process, eg how does a GP access the MAB once the patient has been identified. Request to add contact details for the clinician/patient to use.	**PH**	Complete	
	Request to amend the layout to include drop down sections as it is very lengthy and refers to boxes.		Complete	
TAM323 Nausea and vomiting (Paediatric)	Note to be added to say droperidol is every six hours and to give a maximum dose of dexamethasone of 4mg.	**PH**	Complete	
TAM report	Funding bid to be escalated so that TAM is properly resourced. PH, AL and DS to meet up to take this forward.	**PH/AL/DS**	In progress	

5. FOLLOW UP REPORT

The follow up report was noted.

6. SUBMISSIONS FOR ADDITION TO HIGHLAND FORMULARY FOR APPROVAL

6.1. SACT Formulary submissions for noting

Medicine Company	Indication	Status SMC/licence/ formulary	Requestor	Comments
Trifluridine tipiracil (Lonsurf) film-coated tablets, 15mg/6.14mg, 20mg/8.19mg, Servier	In combination with bevacizumab for the treatment of adult patients with metastatic colorectal cancer (CRC) who have received two prior anticancer treatment regimens including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and/or anti-EGFR agents.	SMC2654 – accepted for use	Catriona Hoare, Cancer Care Pharmacist - Oncology	**ACCEPTED**
Pembrolizumab (Keytruda) 25mg/ml concentrate for solution for infusion, Merck Sharp & Dohme UK Limited	As monotherapy for the adjuvant treatment of adults with non-small cell lung carcinoma who are at high risk of recurrence following complete resection and platinum-based chemotherapy. **SMC restriction:** adults whose tumours express programmed death-ligand 1 (PD-L1) with less than 50% (0 to 49%) tumour proportion score (TPS).	SMC2689 – accepted for restricted use	Catriona Hoare, Cancer Care Pharmacist - Oncology	**ACCEPTED**
Relugolix (Orgovyx) 120mg film-coated tablets, Accord-UK Ltd	• for the treatment of adult patients with advanced hormone-sensitive prostate cancer. • for the treatment of high-risk localised and locally advanced hormone dependent prostate	SMC2678 – accepted for use	Catriona Hoare, Cancer Care Pharmacist - Oncology	**ACCEPTED. However to be resubmitted using full submission form**

	cancer in combination with radiotherapy. • as neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced hormone dependent prostate cancer.			
Selinexor (Nexpovio) 20 mg film-coated tablets, Menarini Stemline UK Ltd	In combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.	SMC2673 – accepted for use	Jenna Baxter, Lead Cancer Care Pharmacist - Haematology	**ACCEPTED**
Selinexor (Nexpovio) 20 mg film-coated tablets, Menarini Stemline UK Ltd	In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.	SMC2673 – accepted for use	Jenna Baxter, Lead Cancer Care Pharmacist - Haematology	**ACCEPTED**

6.2. Non SACT Formulary submissions

6.3. Ritlecitinib (Litfulo®) hard capsules 50mg, Pfizer Ltd (SMC2610)
Submitted by: Alex Morrison, Lead Pharmacist for Homecare
Indication: For the treatment of severe alopecia areata in adults and adolescents 12 years of age and old.
Comments: SM is not in support of this submission as the drug has serious adverse effects. Noted that skin conditions are very visible and do have a big psychological impact. There should be discussion and consideration regarding treatment with patients. There should be robust monitoring that needs to be demonstrated to be in place.
Comment received from Dermatology Team: it is SMC approved and they are under tremendous pressure to make it available. JAC inhibitors are not without risk and arguably alopecia is not life threatening, unless the psychological impacts are profound for the individual. Patients will be counselled on the risks and it would be patient choice as to whether they wish to commence treatment. It will have capacity implications, but patient numbers are small.
Note: NHS Highland is not compelled to use SMC approved medicines, the service needs to have capacity. What service details are in place; such as, patient checklist, monitoring requirements? Would need to have evidence of this prior to the medication being supplied.
ACCEPTED
Action

6.4. Mavacamten (Camzyos®) capsules, Bristol Myers Squibb Pharmaceuticals Ltd (SMC2618)
Submitted by: Peter Clarkson, Consultant Cardiologist
Indication: Treatment of symptomatic (New York Heart Association, NYHA, class II to III) obstructive hypertrophic cardiomyopathy (oHCM) in adult patients.
Comments: To note that genetic testing is available in Scotland. Are there any other responsibilities for Primary Care other than prescribing of this medication?
ACCEPTED
Action

6.5. Aflibercept (Eylea®) (30.1mg/263microlitres) 114.3mg/mL solution for intravitreal injection. Dose = 8mg in 70microlitres, Bayer Plc (SMC857/13, 954/14, 1003/14 and 1074/15)
Submitted by: Anjli Mehta, Lead Pharmacist General Surgery, Ophthalmology & General Surgery
Indication:
- in adults for the treatment of neovascular (wet) age-related macular degeneration.
- for adults for the treatment of visual impairment due to macular oedema secondary to central retinal vein occlusion.
- for adults for the treatment of 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) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline.
- for adults for the treatment of visual impairment due to macular oedema secondary to branch retinal vein occlusion.

Comments: This medicine is already on the formulary. This is a request for a different strength that has cost implications and therefore submitted for ratification. The 8mg strength will result in fewer administration episodes, which would be preferable for patients. At present this 8mg strength will be more cost-effective, however, biosimilars are expected end of 2025/start of 2026. These are likely to then be more cost effective. Predicted over 2 years the service is expected to break even with cost. The service will switch patients to the 8mg preparation, based on their clinical need, rather than simply convenience.

ACCEPTED

6.6. Doxylamine with pyridoxine (Xonvea®) tablets 10mg/10mg, Exeltis UK Ltd (SMC2140 Not recommended for use in NHSScotland)

Submitted by: Dr Leena Thomas, Consultant, Obstetrics and Gynaecology

Indication: The treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management and other first line antiemetics.

Comments: Comments received pre subgroup: SM does not support this submission as it is an expensive combination of what are essentially two old and inexpensive drugs.

Comments received from the service to support this submission include: This is the only licensed treatment for this indication in the UK. Although used first line, eg NHS England, here it would be used third line before steroids, which are known to cause congenital and neurological abnormalities in pregnancy; next step is termination of pregnancy. This is considered to be a lifesaver before using steroids or opting for termination of pregnancy. Numbers are expected to be low, fewer than 20 per year, with cost implications counteracted by expected reduction in: recurrent admissions, prolonged hospital stays, steroids and terminations. To note that the following alternative antihistamines (to doxylamine) are not appropriate in pregnancy: class C phenothiazines, hydroxyzine, diphenhydramine. It is recommended in NICE NG201: Antenatal Care, and RCOG Green top guidelines: The management of nausea and vomiting in pregnancy.

TAMSG comments: This medicine is not recommended by SMC and therefore there needs to be adequate justification for addition to the formulary. Agreed that it could be cost-saving by reducing hospital admission and reducing length of stay, however there is very poor evidence and cost effectiveness information is not robust. Doxylamine is not available as a single product but as a first generation antihistamine; could other antihistamines be used alongside pyridoxine? In practice promethazine once daily is used first line. On the submission form why do patient numbers increase? No clinical benefit has been demonstrated. To note NICE (2021) Antenatal care (nice.org.uk) - *There was evidence on a wide variety of pharmacological treatments, many of which are commonly used in current practice. The evidence on the medicines varied in quality and for some medicines, no evidence was found. Metoclopramide hydrochloride was supported by good quality evidence showing that it was effective in improving symptoms. Ondansetron was also found to be effective in improving symptoms. A combination drug with pyridoxine and doxylamine is currently the only drug licensed for this indication, but the evidence is very old and of low quality and did not show a convincing effect on symptom improvement. Evidence on histamine H1 receptor antagonists was of very low quality and not particularly convincing. Studies on pyridoxine hydrochloride showed differing results, with larger trials showing no improvement in symptoms. No evidence was identified on the effectiveness of cyclizine hydrochloride alone in pregnant women*.

REJECTED

6.7. Mucus clearance device (Aerobika®), Trudell Medical UK Ltd

Submitted by: Judith Colligan, Respiratory Physiotherapist

Indication: To aid the loosening and removal of mucus build-up in the lungs for short and long term respiratory conditions, eg, cystic fibrosis and COPD. For adults and children.

Comments: This is a licensed medical device. The submission is to formalise what happens in practice and to highlight that this is the preferred product. It is usually provided through respiratory clinics or by respiratory physios. It is available via PECOS, rather than being prescribed.

ACCEPTED

6.8. Clonidine tablets 25 microgram and oral solution 50 microgram/5mL

Submitted by: Shiromi Gallella, Consultant Community Paediatrician

Indication: Sleep latency in paediatrics.

Comments: This is an off-label use of a licensed medicine. Specialist initiation only.

Pre subgroup comment: SM is reluctant to support this addition.

Service comments in support of this application: This is only to be used in very complex patients and is widely used in other health boards. It improves quality of life and is already used in practice.

TAMSG comments: Budget impact information is missing from the submission; this is needed prior to decision making. A clear pathway needs to be in place. The evidence base is confusing and includes

particular patient groups that this product is most effective for, which may not reflect the patient population being treated according to this submission. The oral solution is expensive; therefore this should not be used when the tablets can be. Is the oral solution formulation licensed? (Post subgroup comment: Yes, this is licensed). The sleep disorder guidance for children is under review and is due to be submitted to the December meeting. This will include place in therapy for clonidine. Need to ensure that specialist initiation only is clearly stated, with direction on which formulation should be used when. It would be better to wait for the guidance to be ratified with the place in therapy clarified and then the formulary submission can be revisited alongside the guidance.

ACCEPTED pending

Action

7. FORMULARY

7.1. New: F386 Compression hosiery formulary: Argyll & Bute only

ACCEPTED

8. FORMULARY MINOR ADDITIONS/DELETIONS/AMENDMENTS

Noted and approved. Tenecteplase will still be the drug of choice in thrombectomy. Noted that tenecteplase has just had its license extended to stroke thrombolysis and has just been approved through the abbreviated submission route to SMC. PH to discuss with Gethin Williams regarding monograph. A thrombectomy pathway is being developed.

Additionally agreed to remove prescribing restrictions for dapagliflozin. CKD and HF to match 'general prescribing' prescribing status as that for diabetes.

9. FORMULARY REPORT

No new report available.

10. SMC ADVICE

Noted.

11. NEW TAM GUIDANCE FOR APPROVAL

11.1. TAM660 Milk allergy (Paediatric Guidelines)

ACCEPTED

11.2. TAM656 Management of medical chest drains

ACCEPTED

11.3. TAM658 Time critical medicines

ACCEPTED

11.4. AMT192 Outpatient Antibiotic Therapy (OPAT)

- Audience to be amended to include Primary Care.

ACCEPTED

Action

11.5. TAM662 Major haemorrhage protocol (Argyll and Bute)

ACCEPTED

11.6. TAM661 Finerenone in diabetic kidney disease

ACCEPTED

11.7. TAM657 Ulcerative colitis

ACCEPTED

12. GUIDELINE MAJOR AMENDMENTS

12.1. TAM636 Food allergy referral (Paediatrics Guidelines)

ACCEPTED

12.2. TAM637 Egg allergy (Paediatrics Guidelines)

ACCEPTED

12.3. TAM336 Infant Feeding Difficulties Clinic (IFDC) & Paediatric Infant Feeding Allergy Clinic (IFAC) (Paediatric Guidelines)

- There are a few outstanding items to be clarified including cross-referencing with other current guidance on TAM. Any further amendments will be submitted to the December Subgroup.
- Change SCI store to SCI gateway.

ACCEPTED
Action

12.4. AMT153 Scarlet Fever (Antimicrobial)
ACCEPTED

12.5. AMT156 Aspiration Pneumonia (Antimicrobial)
ACCEPTED

12.6. AMT179 Acute lower urinary tract infection in adults (no fever or flank pain) (Antimicrobial)
ACCEPTED

12.7. AMT180 Acute upper urinary tract infection (pyelonephritis/urosepsis) (Antimicrobial)
ACCEPTED

12.8. TAM290 Hyperkalaemia

- Under resources, the link for the dietary sheet is not working.
- Could guidance relevant to Primary Care be developed? PH to escalate request to Claire Copeland and Thomas Ross.

ACCEPTED
Action

Going forward to aim to have all documents that are to be printed to be developed by Medical Illustration for standardisation of format.

13. GUIDELINE AMENDMENTS

Noted and approved.

14. TAM REPORT

Report noted as below:

- The amount of out of date guidance is still on a downward trend.
- Diabetic guidance to have link to self-management resource added, as per standard.

Action

15. ENVIRONMENT

Environmental impact (eg packaging etc) is difficult to assess and is not well documented in submissions. There is no standardised information on packaging that submitters can refer to. Currently we are the only Formulary in Scotland that attempts to find out environmental impact but it is difficult information to obtain. It is hoped that SMC might bring environmental impact into decision making, eg, using a health economics approach.

16. NHS WESTERN ISLES

Nothing to report.

17. ANY OTHER COMPETENT BUSINESS

- *For information: Autumn Edition the Pink One*
  Future editions to be included with Subgroup papers as a PDF version. Discussion to take place outwith this meeting as to why it is confidential to the NHS. PH to contact Sarah Buchan and Boyd Peters.
- *For information: Update on NCMAG advice on chemoprevention for breast cancer*
  At a previous subgroup, anastrozole for the prevention of breast cancer was discussed, a submission had been withdrawn due to awaiting NCMAG advice. It has now been accepted for use along with other medications for the prevention of breast cancer by NCMAG. The submitter has been contacted to see if a submission(s) is to be forthcoming, however there are service implications that need to be addressed first.
- *Shortage notification added to Highland Formulary monographs*
  Weekly meetings now take place between primary, secondary and Community pharmacy to discuss shortages.
  Action

18. DATE OF NEXT MEETING

Next meeting to take place on Thursday 5 December 2024, 14:00-16:30 via TEAMS.

Actions agreed at TAM Subgroup meeting

Minute Ref	Action Point	Action by
Ritlecitinib (Litfulo®) hard capsules 50mg, Pfizer Ltd (SMC2610) *Back to minutes*	• Service to demonstrate that there is an adequate checklist in place to enable patients to make an informed decision based on the benefits and risks of treatment and to enable to the service to identify those patients for whom the medication is and is not appropriate for. • Service to demonstrate that there is adequate monitoring process in place as per the requirements for the safe provision of the medication. These items, as they are owned by the specialist service and are not for publication on TAM, are not required to be submitted to TAMSG for approval, this is just for information.	**PH**
Mavacamten (Camzyos®) capsules, Bristol Myers Squibb Pharmaceuticals Ltd (SMC2618) *Back to minutes*	At present, due to availability, this medicine is restricted to Hospital Use Only. Once this becomes more widely available, please confirm who will be responsible for: • Pre-treatment screening • Monitoring requirements • Clinical review • Cessation. As this will become Specialist initiation only, assume that this will be the specialist's team responsibility. Please confirm.	**PH**
Clonidine tablets 25 microgram and oral solution 50 microgram/5mL *Back to minutes*	• Submission will be reassessed at December TAMSG along with the sleep disorder guidance to ensure appropriate place of therapy is stated. • Budget impact information to be completed in the formulary submission.	**PH**
AMT192 Outpatient Antibiotic Therapy (OPAT) *Back to minutes*	Audience to be amended to include Primary Care.	**PH**
TAM336 Infant Feeding Difficulties Clinic (IFDC) & Paediatric Infant Feeding Allergy Clinic (IFAC) (Paediatric Guidelines) *Back to minutes*	Change SCI store to SCI gateway.	**PH**
TAM290 Hyperkalaemia *Back to minutes*	• Under resources, the link for the dietary sheet is not working. • Could guidance relevant to Primary Care be developed? PH to escalate request to Claire Copeland and Thomas Ross.	**PH**
TAM report *Back to minutes*	Diabetic guidance to have link to self-management resource added, as per standard.	**PH**
AOCB – *For information: Autumn Edition the Pink One* *Back to minutes*	• Future editions to be included with Subgroup papers as a PDF version. • Discussion to take place out with this meeting as to why it is confidential to the NHS. PH to contact Sarah Buchan and Boyd Peters.	**PH**