

North Yorkshire & York Area Prescribing Committee

Wednesday 7th September 2022
2pm – 4.30pm, virtual meeting via Microsoft Teams

Present

Name	Job Title	Organisation	Apr 2022	May 2022	Jul 2022	Aug 2022	Sep 2022
Ken Latta	Head of Medicines Optimisation	North Yorkshire Place	Y	Y	Y	Chris Ranson	Y
Dr Tim Rider	GP Prescribing Lead	North Yorkshire Place	Apols	Y	Y	Y	Y
Laura Angus	Head of Medicines Optimisation and Interim Chief Pharmacist at Humber, & North Yorkshire ICS	City of York Place	Y	Y	Y	Apols	Y
Dr Shaun O'Connell	GP Lead for Acute Service Transformation	City of York Place	Y	Y	Y	Apols	Apols
Dr William Ovenden	GP	City of York Place	Y	Apols	Y	Y	Apols
Kate Woodrow	Chief Pharmacist	Harrogate and District NHS Foundation Trust	Y	Apols	Apols	Y	Apols
Dr Ben Walker	Consultant and D&T Chair	Harrogate and District NHS Foundation Trust	Apols	Y	Y	Y	Apols
Dr S Brotheridge	Consultant	Harrogate and District NHS Foundation Trust	X	X	X	X	X
Stuart Parkes	Chief Pharmacist	York & Scarborough Teaching Hospitals NHS Foundation Trust	Y	Y	Y	David Preece	Y
Dr Chris Hayes	Consultant and D&T Chair	York & Scarborough Teaching Hospitals NHS Foundation Trust	Y	X	Apols	Y	Y
Tracy Percival	Formulary Pharmacist	South Tees Hospitals NHS Foundation Trust	Laura Tweddle	Y	Apols	Y	Y
Richard Morris	Deputy Chief Pharmacist	Tees, Esk and Wear Valleys NHS Foundation Trust	Y	Y	Y	Chris Williams	Y (till item 8)
Shona McIlrae	Consultant Psychiatrist	Tees, Esk and Wear Valleys NHS Foundation Trust	X	X	X	X	X
Angela Hall	Public Health representative	North Yorkshire County Council	Apols	X	X	Y (Till 3pm)	Kurt Ramsden
Anita Dobson	Public Health representative	City of York Council	Y (From 3pm)	Y (Till 3.30pm)	Apols	Y	Apols
Alison Levin	Finance representative	North Yorkshire Place	Apols	Kathryn Shaw-Wright	Apols	Kathryn Shaw-Wright	Kathryn Shaw-Wright
Steve Jordan (till Jan 2022)	Contracting representative	North Yorkshire Place	X	X	X	X	X
Hazel Mitford	Lay/patient representative		Y	Y	Y	Y	Y
Gavin Mankin (Professional Secretary)	Principal Pharmacist Medicines Management	Regional Drug & Therapeutics Centre, Newcastle	Y	Y	Y	Y	Y
Chris Ranson	Lead Medicines Management Pharmacist: Commissioning and Formulary	North Yorkshire Place	Y	Y	Y	Susan Broughton	Y
Faisal Majothi	Medicines Optimisation Pharmacist	City of York Place	Y	Y	Y	Y	Y
Jane Crewe	Formulary Pharmacist	York & Scarborough Teaching Hospitals NHS Foundation Trust	Y	Y	Y	Apols	Y
Sara Abbas-Llewelyn / Emily	Formulary Pharmacist	Harrogate and District NHS Foundation Trust	X	X	X	X	X

Parkes							
Ian Dean	LPC Representative		Y	Y	Y	Y	Apols
Dr Sally Tyrer	LMC Representative		X	Apols	X	X	X
Sara Moore	Deputy Chief Pharmacist	Harrogate and District NHS Foundation Trust	X	Y	Y Kate Woodrow from 4.55pm	Apols	Y

In attendance

Barry Ingram – RDTC – sharing papers on screen via MS Teams

The meeting was quorate with 11 out of 15 currently appointed voting members (or their deputies) in attendance present throughout.

APC members and attendees were reminded to keep detailed discussions confidential to allow free and full debate to inform unencumbered decision making. Discretion should be used when discussing meetings with non-attendees and papers should not be shared without agreement of the chair or professional secretary, to ensure confidentiality is maintained.

The meeting was chaired by Tim Rider.

Part 1

1. Apologies for absence and Quoracy Check

Ben Walker, Kate Woodrow, Ian Dean, William Ovenden, Shaun O'Connell

2. Declarations of Interest

Declarations of interest:

The Chair reminded subgroup members of their obligation to declare any interest they may have on any issue arising at committee meetings which might conflict with the business of the APC.

Declarations declared by members of the APC are listed in the APC's Register of Interests. The Register is available via the professional secretary.

Declarations of interest from today's meeting:

Stuart Parkes – Item 12 - Stuart Parkes has taken part in an education event sponsored by Novartis (manufacturers of Lucentis) – agreed could present item but take no part in decision.

3. Minutes of Previous APC & Decision Summary of Meeting Held 3rd August 2022 (+outcome of HNY IMOC)

The minutes of the August 2022 APC were approved as true and accurate record.

It was confirmed that the HNY IMOC has approved the recommendations from the August 2022 APC meeting with exception of the NY&Y Type 2 Diabetes guidance and the updated NICE gout guidance.

APC discussed current vacancies in membership and non-attendance.

ACTION:

- **Medicines Management Team to seek new members to fill current gaps in APC membership and follow-up non-attendance.**

Noted that change in RAG status of Sacubitril/Valsartan will need communicating to GP practices.

ACTION:

- **Medicines Management Team to communicate change in RAG status of Sacubitril/Valsartan to primary care.**

Noted that error in August 2022 decision summary and fidaxomicin granules should have same AMBER SR status as tablets. This will be corrected in this month's APC decision summary.

4. **Matters Arising Not on The Agenda & Declarations of AOB**

AOB – update re NY&Y Antimicrobial guidelines.

5. **Action Log**

Formulary Updates – NICE TA + MHRA DSU June 2022. Romosozumab, Cyclogest®, Lyumjev®, Sacubitril/Valsartan, Fidaxomicin

JC/SAL to update the formulary websites now decision approved by IMOC.

Glucagon prefilled pen (Ogluo®)

On today's agenda.

Hydrocortisone MR (Efomdy®)

Decision deferred at August 2022 APC to fully appraise evidence around diurnal variation and steroid sparing effect. No update available.

Type 2 diabetes guidance incorporating earlier place in therapy of SGLT2 inhibitors

FM confirmed Hb1Ac thresholds for treatment escalation are correct and match NICE, and guidance submitted to IMOC for approval on this basis after confirmation with Tim Rider. Noted that IMOC did not approved this guidance as need for one single piece of ICS guidance, and Humber APC proposed guidance is different. Work is ongoing to produce one guidance for the ICS.

Outstanding Actions from Previous APC Meetings

Formulary status of alcohol dependence drugs for VoY CCG - Acamprosate and Disulfiram

Work still in progress.

TEWV Anxiety Guidelines – updated

JEC/SAL to update the formulary websites once approved by VoY CCG – still to be actioned as not updated on TEWV website.

CR to add link to TEWV Anxiety Guidelines on APC website – still to be actioned as not updated on TEWV website.

County Durham & Tees Valley APC Cinacalcet SCG

RDTc still to discuss with /KL differences in monitoring in Cinacalcet SCG between CD&T and NY&Y outside of the meeting.

North Yorkshire and York APC – Updated Terms of Reference and Scheme of Delegation

RDTc/LA to work further on tidying up language in NY&Y APC Terms of Reference and bring to future APC

LA and SP have discussed high-cost drugs and their approval under current block arrangements outside of the APC. New formulary application forms highlights where issues might occur. ITEWM NOW CLOSED.

Drugs for POTS (ivabradine, fludrocortisone, desmopressin, midodrine, pyridostigmine)

On today's agenda.

NHS National Patient Safety Alerts - Inadvertent oral administration of potassium permanganate

Included in Medicines Quality & Safety Group newsletter. ITEM NOW CLOSED.

Formulary Updates – NICE TA + MHRA DSU April/May 2022. Efudix, Imiquimoid, Otigo, Lenzetto, Phosphate Binders, Lixisenatide

Formulary websites now updated. ITEM NOW CLOSED.

Eye Chapter Formulary Alignment

Formulary websites now updated. ITEM NOW CLOSED.

Hydroxychloroquine and Chloroquine Retinopathy: Recommendations on Monitoring 16 December 2020 - Updated RCOphth guidelines

Awaiting RMOC final guidance and national SCG template was published in July 2022. Needs discussion how national SCG might be adopted locally and noted this work is underway.

Melatonin YSTHFT Shared care

Still to progress paper due to current work pressures

Part 2 – Governance

6. NY&Y APC Formulary Application Form - updated

The NY&Y APC Formulary Application Form has been updated to mirror that of Humber APC and to try to improve the APC decision making process.

Hopefully, the form is clearer and easier to use/navigate as a result. An online version of the form via MS Forms has been developed. It was discussed and agreed that paper easier to share between authors/contributors for completion/comments, and easier to upload as an agenda item. Therefore, proposal is to proceed with a MS Word based form for now which can easily be shared electronically and allows multiple people to work on the same formulary application.

The updated form was approved by the APC subject to typos being corrected.

The professional secretary will ensure that submitted forms are fully completed and use of “non-applicable” is kept to a minimum.

ACTION:

- **RDTc to circulate approved form to APC members.**
- **CR to add approved form to APC website.**
- **JC to add approved form to Y&S formulary website.**

Part 3 – Mental Health

7. TEWV Drug & Therapeutics Committee Feedback – July 2022

RM presented to the APC a briefing report highlighting the main issues discussed at the recent TEWV D&T.

Part 4 – Formulary Issues

8. Appeals Against Previous APC Decisions

None received.

9. Formulary NICE TAs and MHRA Drug Safety Update – July 2022

The drugs in the following TAs to be reflected in the formulary as RED drugs in the relevant chapters with links to the TAs:

- TA808: Fenfluramine for treating seizures associated with Dravet syndrome
- TA809: Imlifidase for desensitisation treatment before kidney transplant in people with chronic kidney disease
- TA810: Abemaciclib with endocrine therapy for adjuvant treatment of hormone receptor-

- positive, HER2-negative, node-positive early breast cancer at high risk of recurrence
- HST21: Setmelanotide for treating obesity caused by LEPR or POMC deficiency

The drugs in the following TAs to be reflected in the formulary as NOT APPROVED for this indication in the relevant chapters with links to the TAs:

- TA806: Belimumab for treating lupus nephritis
- TA811: Duvelisib for treating relapsed or refractory chronic lymphocytic leukaemia after 2 or more treatments (terminated appraisal)

All the above TAs are NHSE-commissioned, therefore would have no cost impact to the ICB.

The ICB commissioned drugs in the following TAs to be reflected in the formulary as RED drugs for this indication in the relevant chapters with links to the TAs:

- TA803: Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs

The ICB commissioned drugs in the following TAs to be reflected in the formulary as GREEN drugs for this indication in the relevant chapters with links to the TAs:

- TA805: Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides – referred to IMOC for final decision due to cost impact.

It was agreed that further work on the local cost impact for TA807: Roxadustat for treating symptomatic anaemia in chronic kidney disease was required for the next APC meeting.

Medicines Safety (MHRA drug safety update – July 2022)

The group noted the drug safety updates for July 2022. The links are to be added to the relevant sections of the formulary.

ACTION:

- **JC/SAL to update the formulary websites.**

10. Other Formulary Issues

Nil this month.

11. New Drug Applications

Diazoxide for Chronic Intractable hypoglycaemia

A request from HDFT to add diazoxide tablets for Chronic Intractable hypoglycaemia to the formulary was presented the APC. It was noted that is already on the Y&S formulary for this indication but does not have a RAG status.

The RAG status in surrounding areas was noted.

After discussion it was agreed to defer a decision to the next APC as more information on ongoing monitoring is required.

ACTION:

- **SM to get further information on ongoing monitoring for Oct 2022 APC.**

Biologic treatments for pityriasis rubra pilaris

A request from YSFT supported by HDFT to add Adalimumab, Secukinumab, Ustekinumab, Risankizumab, and Guselkumab to the formulary as an unlicensed indication for pityriasis rubra pilaris (PRP) was presented to the APC

Infliximab (an anti TNF) was approved by the APC for PRP in October 2021. However, infliximab is an IV therapy which is difficult to arrange at York due to reduced capacity on day wards.

Evidence is available to support the use of the s/c biologics therapies which can be self-administered.

A proposed treatment pathway was also presented to the APC. It was estimated there would be 2-3 patients per year.

It was noted that costs currently fall under secondary care block contract and could be absorbed within current dermatology budget as patient numbers are low. It therefore does not final sign off from IMOC for this reason and because costs within level of delegated authority of APC.

The request was approved by the APC as RED drugs for this indication along with the supporting treatment pathway.

ACTION:

- **JC/SAL to update the formulary websites.**

Glucagon prefilled pen (Ogluo®)

The APC discussed the formulary application and the further evidence collated by the applicant since the last APC meeting.

At the August 2022 APC meeting the application was refused on the basis of significant cost difference over current Glucagen® product and no evidence presented of critical incidents due to time to reconstitute current product.

Nationally there are situations where serious, life changing illness and disability results from severe hypoglycaemia. There is not any data that the new devices reduce this yet but the view of clinicians is that these devices will reduce risk.

No references have been located which specifically describe critical incidents due to time to reconstitute current product. Given this is an emergency treatment this kind of information would be difficult to collect or prove and would not be controlled in any way. Publications have however looked at “simulated administration” and identified problems with the current kits, some of these can be overcome by using an autoinjector device.

All agreed Ogluo® may offer advantages over current product in that it is a pre-filled pen so does not require reconstitution before administration during hypoglycaemic event. It also does not require fridge storage. But concerns expressed that increased cost may not be justified. There appears to lack of reported incidents/serious adverse outcomes with current product, though acknowledge this information may be difficult to collect and may not be reported. The main question to the APC wanted answered do advantages of this new product justify the increased cost.

After much discussion, the APC agreed to the following to do the following before considering the product again at a future APC.

- See if this product has been considered by other APCs in the UK and what the outcome was.
- Check if MSO Network, MHRA and national patient safety alert system are aware of any critical incidents with current glucagon product.

ACTION:

- **RDTG to see if this product has been considered by other APCs in the UK and what the outcome was.**
- **LA to check if MSO Network, MHRA and national patient safety alert system are aware of any critical incidents with current glucagon product.**

12. Faricimab (NICE TA 799 and 800) and Ranibizumab biosimilar

NICE TA 799 and 800 for faricimab in wet Age-related macular degeneration (wAMD) and Diabetic Macular Oedema (DMO) were published in June 2022

Faricimab has the advantage of having a potentially longer duration of effect which may mean increased intervals between injections. It may be given 16 weekly after an initial loading phase. This is particularly positive given the current capacity constraints in ophthalmology.

In liaison with ophthalmologists in both Trusts, initially it is proposed to be used for patients on 4-6 weekly injections of Eylea (aflibercept) and Lucentis (ranibizumab). After clinicians have gained experience it is proposed to investigate using for new initiations.

In terms of safety there are no issues with inflammatory disorders that were raised when brolicizumab was considered last year.

The NHSE Commissioning Recommendations following the procurement of medical retinal

vascular medicines were presented to the APC. In terms of implementation locally it is planned that patients on Lucentis are switched to biosimilar ranibizumab, it is proposed that this commences from September 2022. The ophthalmologists do not feel it is clinically appropriate to either switch patients from Eylea to biosimilar ranibizumab or start new initiations on biosimilar ranibizumab.

Rationale:

- Patients on Lucentis require more frequent injections than those on Eylea
- Switching from Eylea to Lucentis would require monthly loading for 3 months and this is not supported by the ophthalmology community or by commissioning document.
- There are constraints on capacity in ophthalmology outpatient departments

This proposal was approved by the APC along with the local implementation plan for the NHSE Commissioning Recommendations following the procurement of medical retinal vascular medicines

ACTION:

- **JC/SAL to update the formulary websites.**

13. Drugs for POTS

The APC discussed how to progress the formulary application for drugs for POTS. It was agreed to audit prescribing in primary care to inform the discussion. Noted that discussions around commissioning of the service continue, and the outcome of these discussions will be brought back to future APC.

14. Compassionate Use/Free of Charge Scheme Requests

Nil this month.

15. RMO Update

Nil this month.

Part 5 – Shared Care and Guidelines (non-Mental Health)

16. Shared Care Guidelines for Approval

Nil this month.

17. Atopic Dermatitis NICE TA 814

NICE TA814 was published on the 5/8/22 and supports the use of abrocitinib, upadacitinib and tralokinumab for use in atopic dermatitis.

These are additional options for moderate to severe atopic dermatitis to the current medicines in the pathway dupilumab and baricitinib and will be used after at least one systemic immunosuppressant.

Abrocitinib and upadacitinib may be used in patients over 12 years of age but tralokinumab is only licensed in adults.

The atopic dermatitis pathway has been updated to include these agents. NICE does not give a preference but states that the evidence for baricitinib is inferior to dupilumab whereas the newly approved agents are similar or better however there are no direct head-to-head studies.

Patient factors influencing treatment options include age, renal function, history of VTE which would contra-indicate JAK inhibitors and route of administration. If all things are equal, then the more cost-effective agent should be used.

In terms of implementation, abrocitinib is in the Early Access to Medicines Scheme so implementation of NICE TA should be within 30 days. Tralokinumab and upadacitinib have the standard 90 days implementation.

The cost impact will be an overall reduction in cost for the pathway as a whole.

The updated pathway was approved by the APC.

ACTION:

- **JC/SAL to update the formulary websites.**

Part 6 – Other Items of Business

18. Inclisiran in primary care

APC noted the ongoing issues with GP refusing to initiate inclisiran. This has been escalated nationally via the AHSN.

Part 7 – Standing Items (for information only)

19. TEWV D&T Minutes – May 2022

Not yet available.

20. York & Scarborough Trust Drug and Therapeutics Committee Minutes – since July 2022

Not yet available.

21. Harrogate Trust Medicines and Therapeutics Group Minutes – since May 2022

Not yet available.

22. County Durham & Tees Valley APC Minutes – May 2022

Not yet available.

23. West Yorkshire & Harrogate ICS APC Minutes – since April 2022

Not yet available.

24. Humber APC Minutes

Not yet available.

25. RDTC Monthly Horizon scanning – August 2022

Circulated for information.

26. TEWV Medicines Optimisation Annual Report 21-22

Circulated for information.

Any Other Business

NY&Y Antimicrobial Guidelines

An update was given regards the status and direction with regards to the NYY antimicrobial guidelines for primary care. Existing guidelines are overdue an update and contain some out-of-date content. Considering working on a consistent H+NY positions. In the interim the proposal is to remove the old version and direct users to the current PHE version. This proposal was supported by the APC.

The NY&Y Antimicrobial group will be re-established to update local guidelines. Timescales for updating the NY&Y guideline will be agreed at the next APC.

Date and time of next meeting

Wednesday 5th October 2022, 2pm – 4.30pm, Virtual Meeting via Microsoft Teams