

North Yorkshire & York Area Prescribing Committee

Wednesday 1st February 2023
2pm – 4.30pm, virtual meeting via Microsoft Teams

Present

Name	Job Title	Organisation	Sep 2022	Oct 2022	Nov 2022	Dec 2022	Feb 2023
Ken Latta	Head of Medicines Optimisation	North Yorkshire Place	Y	Y	Y	Y	Rachel Ainger
Dr Tim Rider	GP Prescribing Lead	North Yorkshire Place	Y	Y	Y	Y	Y
Laura Angus	Head of Medicines Optimisation and Interim Chief Pharmacist at Humber, & North Yorkshire ICS	City of York Place	Y	Apols	Y	Y	Y
Dr Shaun O'Connell	GP Lead for Acute Service Transformation	City of York Place	Apols	Apols	Y	Y	Y
Dr William Ovenden	GP	City of York Place	Apols	Y	Y	Y	Y
Kate Woodrow	Chief Pharmacist	Harrogate and District NHS Foundation Trust	Apols	Y	Y	Y	Y
Dr Ben Walker	Consultant and D&T Chair	Harrogate and District NHS Foundation Trust	Apols	Y	Y	Y	Apols
Stuart Parkes	Chief Pharmacist	York & Scarborough Teaching Hospitals NHS Foundation Trust	Y	Y	Y	Y	Y
Dr Chris Hayes	Consultant and D&T Chair	York & Scarborough Teaching Hospitals NHS Foundation Trust	Y	X	Y (from 3pm)	Y	Apols
Tracy Percival	Formulary Pharmacist	South Tees Hospitals NHS Foundation Trust	Y	X	Y	Y	Apols
Richard Morris	Deputy Chief Pharmacist	Tees, Esk and Wear Valleys NHS Foundation Trust	Y (till item 8)	Y	Apols	Y (till item 9)	Apols
Angela Hall	Public Health representative	North Yorkshire County Council	Kurt Ramsden	Apols	Kurt Ramsden	Kurt Ramsden	Apols
Anita Dobson	Public Health representative	City of York Council	Apols	Y	Y (till 3.15pm)	Apols	Y
Alison Levin	Finance representative	North Yorkshire Place	Kathryn Shaw-Wright	Kathryn Shaw-Wright	Kathryn Shaw-Wright	Jo Horsfall	Jo Horsfall
Hazel Mitford	Lay/patient representative		Y	Y	Y (Till 3pm)	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	Y	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	Y	Y
Sara Abbas-Llewelyn / Emily Parkes	Formulary Pharmacist	Harrogate and District NHS Foundation Trust	X	X	X	X	X
Ian Dean	LPC Representative		Apols	Y	Apols	Y	Y
Dr Sally Tyrer	LMC Representative		X	X	X	X	X
Sara Moore	Deputy Chief Pharmacist	Harrogate and District NHS Foundation Trust	Y	X	Apols	X	For item 17

In attendance

Nil

The meeting was quorate with 10 out of 15 currently appointed voting members (or their deputies) in attendance and 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 Shaun O'Connell.

The APC noted that this would have been Dr Ben Walker's last APC meeting as he is stepping down as HDFT MTG Chair from March 2023. The APC wished to record its thanks for his valued contributions to the APC over the years and for all he has done in support of the medicines/prescribing agenda over the years.

Part 1

1. Apologies for absence and quoracy check

Angela Hall, Kurt Ramsden, Ken Latta, Chris Hayes, Tracy Percival, Richard Morris, Ben Walker

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:

Nil declared.

3. Minutes of previous APC & decision summary of meeting held 7th December 2022

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

4. Outcome of items referred to December 2022 IPMOC

Fostamatinib NICE TA835 was sent by the January 2023 IPMOC to the ICB for approval as delegated authority limits not yet in place for York.

Items referred to IPMOC previously still awaiting confirmation of scheme of delegation for decision-making by IPMOC.

5. Matters arising not on the agenda & declarations of AOB

Nil matters arising.

AOB – nil submitted.

6. Action log

Medical Devices Commissioning and Formulary Position

RDTc to make amendments to previous Y&S MCC formulary position as suggested and publish – completed and ITEM NOW CLOSED.

RDTc to review previous MCC commissioning positions on individual medical devices in Q1 2023/24.

Vulval treatment advice proforma - HDFT

SP/JC to continue to consult with YSFT and adoption before APC makes a decision on approval. To come back to April 2023 APC.

Formulary Updates approved at November 2022 APC

JC/SAL have updated the Y&S and Harrogate formularies. ITEM CLOSED.

Outstanding actions from previous APC meetings

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

RDTCL/LA to work further on tidying up language in NY&Y APC Terms of Reference and bring to future APC once IPMOC terms of reference plus scheme of delegation for ICB decision making around medicines agreed. To come back to May 2023 APC.

Current vacancies in membership and non-attendance.

Work ongoing by medicines management team to seek new members to fill current gaps in APC membership and follow up non-attendance. Awaiting ICB reorganisation to complete. To come back to April 2023 APC.

Bicalutamide RAG status

JC confirm doses and bring amended letter to GPs to next APC.

Feb 2023 update: With regards to the evidence for bicalutamide at 150 mg dose this dose is being used to treat metastatic prostate cancer. Especially where there is high-risk disease, there is advantage to starting full treatment as soon as possible, rather than waiting for the suppression from LHRH (which can take over 3 weeks).

With regards to the letter for primary care, YSFT has the master copy of this and will review.

Diazoxide for chronic intractable hypoglycaemia

KW/SM/JC to develop shared care guideline to be presented to future APC for approval. To come back to May 2023 APC.

Shared care guidelines for approval.

LA/KL to look at implementation/adoption of the transfer of and acceptance of shared care letter appendices in North Yorkshire & York, and report back to a future APC meeting – this was piloted with the recent sodium valproate SCG consultation.

The APC discussed the next steps with the sodium valproate SCG in light of the December 2022 MHRA Drug Safety Update and the subsequent withdrawal of the national sodium valproate template for updating. It was felt that because of the ongoing risks to females, having something in place was better than doing nothing whilst awaiting an updated national template. It was agreed therefore that the sodium valproate SCG in its current form for females should be presented for approval at the next APC with reference to the latest MHRA Drug Safety Update but no more. It was acknowledged that once approved there would be work to be done with providers to support implementation.

Hydroxychloroquine and Chloroquine retinopathy: Recommendations on monitoring 16 December 2020 – updated RCOphth guidelines

No update available.

Melatonin YSTHFT shared care

Still to progress paper due to current work pressures. Noted TEWV SCG currently undergoing review and will come to next APC for comment.

Part 2 – Governance

7. Nil this month.

Part 3 – Mental Health

8. Nil this month.

Part 4 – Formulary Issues

9. Appeals against previous APC decisions

None received.

10. Formulary NICE TAs and MHRA Drug Safety Update – November and December 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:

- TA849: Cabozantinib for previously treated advanced hepatocellular carcinoma
- TA851: Pembrolizumab for neoadjuvant and adjuvant treatment of triple-negative early or locally advanced breast cancer
- TA852: Trifluridine–tipiracil for treating metastatic gastric cancer or gastro-oesophageal junction adenocarcinoma after 2 or more treatments

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:

- TA850: Amivantamab for treating EGFR exon 20 insertion mutation-positive advanced non-small-cell lung cancer after platinum-based chemotherapy

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:

- TA853: Avatrombopag for treating primary chronic immune thrombocytopenia

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

- TA854: Esketamine nasal spray for treatment-resistant depression

The following NICE TAs were received for information:

- TA838: Slow-release potassium bicarbonate–potassium citrate for treating distal renal tubular acidosis (terminated appraisal)
- TA839: Ruxolitinib for treating acute graft versus host disease refractory to corticosteroids (terminated appraisal)
- TA840: Ruxolitinib for treating chronic graft versus host disease refractory to corticosteroids (terminated appraisal)
- TA841: Carfilzomib with daratumumab and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal)
- TA842: Tisagenlecleucel for treating follicular lymphoma after 2 or more therapies (terminated appraisal)
- TA843: Luspatercept for treating anaemia caused by beta-thalassaemia (terminated appraisal)
- TA844: Luspatercept for treating anaemia caused by myelodysplastic syndromes (terminated appraisal)
- TA845: Mepolizumab for treating eosinophilic granulomatosis with polyangiitis (terminated appraisal)
- TA846: Mepolizumab for treating severe hypereosinophilic syndrome (terminated appraisal)
- TA847: Mepolizumab for treating severe chronic rhinosinusitis with nasal polyps (terminated appraisal)
- TA848: Cemiplimab for untreated PD-L1-positive advanced or metastatic non-small-cell lung cancer (terminated appraisal)

Noted that all the above recommendations fall within the delegated authority of the APC.

Medicines Safety (MHRA Drug Safety Update – November and December 2022)

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

ACTION:

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

11. Other formulary issues

Metolazone

The APC was asked if a new formulary application was required for metolazone now that has returned to the UK market as a licensed product following its withdrawal in 2012. The APC agreed that a new full formulary application for the newly licensed metolazone tablets was required so that all the issues (e.g. cost, bioavailability compared to unlicensed form) can be considered.

12. New Drug Applications

Oral minoxidil for androgenic alopecia

This formulary application was originally rejected at the APC meeting in August 2022 on the grounds of equality, as the original application did not include use in males so APC could be open to an equality of access challenge. It was also noted that the majority of topical forms are not approved on the basis of not being an effective use of NHS resources but unlike oral minoxidil they are available to purchase over the counter. The APC said it would accept a resubmission for use in both females and males, and this was presented at this meeting for consideration.

Additional information was presented to the APC for the first time that, in hindsight, the APC should have been aware of at its August 2022 meeting and for this the Chair/secretariat give their apologies.

This additional information is that present commissioning policies across North Yorkshire state that at present North Yorkshire & York do not routinely commission any hair loss treatments and any requests would need to go down the IFR route. The comments in the cover paper for the application “first line options are not listed as an option on the formulary however this is historically what has happened and is happening in practice” appear to be in contravention to the current local NHS commissioning policy.

The APC terms of reference includes a requirement to “ensure that decisions taken about medicines usage are consistent with wider commissioning frameworks where appropriate for the local population”. The existing policy made it difficult for us as an APC to consider this request. There was debate on whether the committee should consider the application at all. The committee decided to do so after a majority open vote.

There were views that it was not logical for the committee to approve a drug for a treatment the local NHS did not commission, and others that the APC could still consider the evidence for the drug’s cost effectiveness in treating androgenic alopecia.

The APC also discussed private prescribing vs NHS prescribing including via the IFR route.

The committee is aware that there is a process of ‘harmonisation’ of the former CCG commissioning policies (also known as thresholds) into single Yorkshire and Humber ICS ones.

The committee was informed that NICE are in the process of reviewing baricitinib for the management of alopecia with a current expected publication date of 25th April 2023. There was mention during the meeting that new NICE guidance on alopecia is being drafted but on checking after the meeting cannot find evidence that NICE are reviewing their guidance in this area, other than around baricitinib.

After much discussion and a closed blind vote the APC but could not reach a consensus on

whether the drug should be commissioned or what RAG status it should have. It was proposed and agreed to defer a decision.

Votes from ten voting members recorded as:

- Amber SR = 2
- Red = 1
- Not approved/Black = 3
- Amber SI = 1
- Abstain = 3

The APC decided that it needs to flag this issue up to the policy review committee so that they can plan in a timely manner when this policy can be reviewed. Clearly, we cannot predict what NICE will say about baricitinib but if it is approved by NICE there should be 90 days to implement the decision, which hopefully will allow time for review of the entire policy.

In summary the APC deferred a decision on the resubmission for oral minoxidil for alopecia to get clarity as to when the current North Yorkshire & York commissioning policies for hair loss will be reviewed in light of the evidence presented in this application and due to the forthcoming NICE TA for baricitinib. The APC was not in a position to make a decision whilst there was this apparent contradiction with North Yorkshire & York commissioning policies.

ACTION:

- **RDTC/SOC/TR to draft and submit a response to the applicant explaining why a decision deferred and apologising for APC not being aware of NY&Y commissioning policy for hair loss previously.**
- **CR to contact Rachel Staniforth to get clarity from the ICB policy alignment group as to timeline for aligning this particular policy across the ICB. Plus, to flag that will need a review in light of forthcoming NICE TA for baricitinib.**

Budesonide orodispersible tablet (Jorveza®) for maintenance treatment of eosinophilic oesophagitis

Jorveza® is licensed for maintenance treatment as per SPC/BNF however at the time the NICE appraisal was completed, the manufacturer only submitted an application for induction not maintenance, hence NICE have only approved for induction.

The APC reviewed the Medicines in Practice publication from the RDTC summarizing the evidence base and current unlicensed treatment options. It noted that published trial data to date is only against placebo, but that the evidence required to gain a product license is set by the MHRA/EMA.

The APC noted that within NY&Y it was expected to be used in five patients per year.

The APC approved the application as an AMBER SI drug for maintenance treatment as the only licensed drug for this indication and number of patients expected to be small. To remain a RED drug as per the relevant NICE TA for induction of remission in eosinophilic oesophagitis. This decision falls within the delegated authority of the APC.

ACTION:

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

Testosterone (Testavan®)

The APC discussed the request for addition of an additional topical testosterone gel, Testavan®, to be added to the formulary. There is the potential for some cost savings compared with existing brands, and it provides an additional brand option in the event of supply issues. The applicator may be seen as a safety advantage especially in light of the January 2023 MHRA Drug Safety Update re topical testosterone, although may be additional plastic waste.

The APC approved the application as an AMBER SR drug.

This decision falls within the delegated authority of the APC.

ACTION:

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

13. Respiratory formulary chapter review

The Respiratory section on the formulary is the second BNF chapter to be aligned across North Yorkshire.

There were a total of 129 drugs listed in this section and 57 that did not have an absolute match. The proposed recommendations are stated within the paper.

It was also identified because of this review that new product requests would be required as follows:

- Lufrobec MDI for management of both asthma and COPD as a replacement to Fostair MDI as it is a third of the price and contains the same constituents.
- Trimbow Nexthaler – this is already available on formulary as an MDI so this would provide a dry powder alternative (note the nexthaler is only licensed for COPD).
- Bevespi Aerosphere 7.2 micrograms/5 micrograms pressurised inhalation for management of COPD as this would provide a LAMA/LABA MDI option for patients unable to use the drug powder options.

These new product requests will be submitted when ready.

The APC approved the proposed recommendations for this section and noted the drugs that require further consideration. This decision falls within the delegated authority of the APC. It should be noted that the ICB has set up a task and finish group to look at aligning adult asthma guidelines/ formulary across the whole of the ICB which is been led by Dr Michael Crooks. This will mean this will be presented at a later meeting although this is likely to be later this year.

ACTION:

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

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. Vitamin D guidance - reviewed and updated

The reviewed NY&Y vitamin D guidance was presented to and approved by the APC subject to the following:

- Include more definition on symptoms of vitamin D deficiency that require a blood test to check vitamin D levels.
- Strengthen language to encourage patients to purchase vitamin D supplements over the counter.

It was noted that no significant changes have been made compared to previous North Yorkshire guidance. This was an update of existing HDFT guidance and it was agreed this should be used as the basis for NY&Y guidance with the addition of information from the York guidance.

ACTION:

- **JC/SAL to update the formulary websites.**
- **CR to update NY&Y guidelines pages.**
- **FM/SM to add in additional information from York guidance.**

18. Dry Eyes Guideline – minor update

The North Yorkshire and York "Prescribing guidance for ocular surface diseases, including dry eye" has had a minor update to include several brands of hypromellose 0.3% eye drops. This is because hypromellose is now a medical device and as such the price can vary widely if prescribed generically. The three brands chosen are the most cost effective available from different manufacturers and give prescribers alternatives should there be any availability issues. The update was approved by the APC. This decision falls within the delegated authority of the APC.

ACTION:

- **JC/SAL to update the formulary websites.**
- **CR to update NY&Y guidelines pages.**

19. Upadacitinib for treating moderately to severely active ulcerative colitis – updated pathway

An updated biologics pathway for severe active Crohn's & moderate to severe Ulcerative Colitis was presented to and approved by the APC. It has been updated to reflect latest NICE guidance TA856 - Upadacitinib for treating moderately to severely active ulcerative colitis. This decision falls within the delegated authority of the APC.

ACTION:

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

Part 6 – Other Items of Business

20. Nil this month.

Part 7 – Standing Items (for information only)

21. TEWV D&T Minutes – November 2022

Not yet available.

22. York & Scarborough Trust Drug and Therapeutics Committee Minutes – since November 2022

Not yet available.

23. Harrogate Trust Medicines and Therapeutics Group Minutes – since September 2022

Not yet available.

24. County Durham & Tees Valley APC Minutes – November 2022

Circulated for information.

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

Not yet available.

26. Humber APC Minutes – December 2022

Circulated for information.

27. Humber APC Decisions & Recommendations – December 2022

Circulated for information.

28. RDTC Monthly Horizon scanning – December 2022 and January 2023

Circulated for information.

Any Other Business

New clinician representation from HDFT

Noted that Dr Victoria Millson will replace Dr Ben Walker from March 2023.

Observing how other APCs function

Suggested was made for some members to attend other APCs to observe how they work. This will be explored outside of the meeting.

Date and time of next meeting

Wednesday 1st March 2023, 2pm – 4.30pm, virtual meeting via Microsoft Teams