

North Yorkshire & York Area Prescribing Committee

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

Present

Name	Job Title	Organisation	Oct 2022	Nov 2022	Dec 2022	Feb 2023	Mar 2023
Ken Latta	Head of Medicines Optimisation	North Yorkshire Place	Y	Y	Y	Rachel Ainger	Y
Dr Tim Rider	GP Prescribing Lead	North Yorkshire Place	Y	Y	Υ	Υ	Y
Laura Angus	Head of Medicines Optimisation and Interim Chief Pharmacist at Humber, & North Yorkshire ICS	City of York Place	Apols	Y	Y	Y	Y (from Item 15)
Dr Shaun O'Connell	GP Lead for Acute Service Transformation	City of York Place	Apols	Y	Y	Y	Y
Dr William Ovenden	GP	City of York Place	Y	Y	Υ	Υ	Y
Kate Woodrow	Chief Pharmacist	Harrogate and District NHS Foundation Trust	Y	Y	Y	Y	Apols
Dr Ben Walker	Consultant and D&T Chair	Harrogate and District NHS Foundation Trust	Y	Y	Y	Apols	Victoria Millson
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	Х	Y (from 3pm)	Y	Apols	Y (from item 10)
Tracy Percival	Formulary Pharmacist	South Tees Hospitals NHS Foundation Trust	Х	Y	Y	Apols	Y
Richard Morris	Deputy Chief Pharmacist	Tees, Esk and Wear Valleys NHS Foundation Trust	Y	Apols	Y (till item 9)	Apols	Y
Angela Hall	Public Health representative	North Yorkshire County Council	Apols	Kurt Ramsden	Kurt Ramsden	Apols	Kurt Ramsden
Anita Dobson	Public Health representative	City of York Council	Y	Y (till 3.15pm)	Apols	Y	Apols
Alison Levin	Finance representative	North Yorkshire Place	Kathryn Shaw- Wright	Kathryn Shaw- Wright	Jo Horsfall	Jo Horsfall	Jo Horsfall
Hazel Mitford	Lay/patient representative	•	Y	Y (Till 3pm)	Y	Υ	Apols
		Non-Voting	Members				
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	Х	Х	Х	Х	Х
Ian Dean	LPC Representative		Y	Apols	Υ	Y	Y
Dr Sally Tyrer	LMC Representative		Х	Х	Х	Х	Х
Sara Moore	Deputy Chief Pharmacist	Harrogate and District NHS Foundation Trust	Х	Apols	Х	For item 17	Y

In attendance

Observing – Dr Anna Schuberth, Palliative Care Registrar

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.

Dr Victoria Millson-Brown the new HDFT D&T Chair and consultant representative from HDFT was welcomed to her first meeting.

Part 1

1. Apologies for absence and quoracy check

Kate Woodrow, Anita Dobson, Hazel Mitford

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 1st February 2023

The minutes of the February 2023 APC were approved as a true and accurate record.

4. Outcome of items referred to February 2023 IPMOC

Nil from February 2023 APC meeting.

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

Oral minoxidil for androgenic alopecia

RDTC/SOC/TR have drafted and submitted 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.

ICB policy alignment group have confirmed they will reviewing this particular policy across the ICB when the NICE TA for baricitinib. So agreed no further action for item for APC until this policy reviewed by the ICB.

Vitamin D guidance - reviewed and updated

FM/SM still to add in additional information from York guidance.

Formulary Updates Approved at February 2023 APC

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

Outstanding actions from previous APC meetings

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 once IPMOC terms of reference plus scheme of delegation for ICB decision making around medicines agreed. To come back to May 2023 APC. Noted meeting arranged with APC membership in late March 2023 to review how the APC operates.

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. Noted meeting arranged with APC membership in late March 2023 to review how the APC operates.

Bicalutamide RAG status

JC confirm doses and bring amended letter to GPs to April 2023 APC.

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

Valproate SCG on today's agenda. ITEM NOW CLOSED.

Medical Devices Commissioning and Formulary Position

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

<u>Hydroxychloroquine and Chloroquine retinopathy: Recommendations on monitoring 16 December 2020 – updated RCOphth guidelines</u>

No update available.

Melatonin YSTHFT shared care

TEWV SCG on today's agenda.

Part 2 - Governance

7. Nil this month.

Part 3 - Mental Health

8. TEWV Drug & Therapeutics Committee Feedback – Jan 2023

Circulated for information.

9. TEWV Depression medication algorithm

Circulated to the APC for comment/consultation. This is an update of existing TEWV guidance to reflect the latest NICE guidance.

The following changes were requested by the APC:

 Discontinuation syndrome – to add in line to blue box at top of document that information on this in an embedded document at the end.

- Trazadone in step 1 to make clear that GPs can start this and when used in combination at this step it is as a hypnotic not at an antidepressant dose.
- Sertraline 100mg dose to make clear this is the minimum effective dose not the starting dose.

Noted that subject to consultation with the County Durham & Tees Valley APC the final version will be approved at the March 2023 TEWV D&T meeting.

10. TEWV Melatonin prescribing / shared care guidelines

Circulated to the APC for comment/consultation. This is an update of existing TEWV guidance. Now includes Adaflex® replacing Circardin® as Adaflex® licensed in children. Circadin® retained in the SCG to cover existing prescribing, Slenyto® retained for its specific licensed indication. Agreed not to include Ceyesto® brand as only available in one strength unlike Adaflex®.

The document has been prepared in the NENC template but TEWV happy to prepare a version with NY&Y branding.

Noted that also now contains de-prescribing guidance for the first time.

The following changes were requested by the APC:

- Circardin® make clearer only for existing patients.
- Make clearer when each product should be used using previous algorithm in current SCG.
- In Part 6 clarify exactly when oral liquid can be used.
- Section 9 change responsibility for height and weight checks to specialist from GP as part of specialist annual review.
- Emphasise that not a lifelong treatment and subject to regular treatment breaks to assess ongoing need.
- Make clear in sections for patient/carer responsibilities that use subject to regular to assess ongoing need.

Noted that subject to consultation with the County Durham & Tees Valley APC the final version will be approved at the March 2023 TEWV D&T meeting.

The APC also discussed what happens when children transition to adult services, and what happens if still a need for melatonin. At this point a review is needed to confirm if melatonin still needed but no service in NY&Y for adults not under mental health to go. Agreed not for APC to discuss/resolve at this meeting today.

11. TEWV Guidance on prescribing psychotropics in child-bearing potential

Circulated to the APC for comment/consultation. This is an update of existing TEWV guidance. The following changes were requested by the APC:

• Strengthen wording in blue box that patients need to be on a highly effective contraception before initiation of any of these drugs.

Noted that subject to consultation with the County Durham & Tees Valley APC the final version will be approved at the March 2023 TEWV D&T meeting.

Part 4 - Formulary Issues

12. Appeals against previous APC decisions

None received.

13. Formulary NICE TAs and MHRA Drug Safety Update – January 2023

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

- TA855: Mobocertinib for treating EGFR exon 20 insertion mutation-positive advanced non-small-cell lung cancer after platinum-based chemotherapy
- TA857: Nivolumab with platinum- and fluoropyrimidine-based chemotherapy for untreated HER2-negative advanced gastric, gastro-oesophageal junction or oesophageal adenocarcinoma
- TA858: Lenvatinib with pembrolizumab for untreated advanced renal cell carcinoma
- TA860: Maribavir for treating refractory cytomegalovirus infection after transplant

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:

TA856: Upadacitinib for treating moderately to severely active ulcerative colitis

The ICB-commissioned drugs in the following TAs were received for information:

 TA859: Angiotensin II for treating vasosuppressor-resistant hypotension caused by septic or distributive shock (terminated appraisal)

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

Medicines Safety (MHRA Drug Safety Update - January 2023

The group noted the drug safety updates for January 2023. The links are to be added to the relevant sections of the formulary.

ACTION:

JC/SAL to update the formulary websites.

14. Other formulary issues

Covid antivirals

Noted to remain RED on the formulary as agreed by HNY IPMOC to reflect only prescribed by specialists via a specific supply model. Noted that supply route changing from Acute Trusts to community pharmacy.

National metabolic formulary

Item deferred for further work.

15. New Drug Applications

Topical morphine for painful wounds

The APC discussed the formulary application received for Morphine Sulphate in intrasite gel (or metronidazole gel) for painful wounds in palliative care.

The following points were considered in reaching a decision:

- Unlicensed indication and product.
- Low patient numbers approx. six patients per year across North Yorkshire and York.
- Information leaflet available from Harrogate but as never formally been considered for inclusion in the formulary.
- Lots of practical issues with use in community:
 - Availability of ready-made product as a special.
 - Variability on cost of ready-made product in community pharmacy with potential additional charges associated with sourcing each time.
 - o Ease of preparing at patient bedside and training of staff to do this.
- Not included in NENC or Yorkshire & Humber Palliative Care Guidelines
- Evidence base consists of single case reports or very small trials with variable results.
- UKIMi Q&A expired March 2011 and no longer on SPS website as a reference source for prescribers.
- Would be ordered in for specific patients as needed and not held as stock.

- Not aware of any recent GP prescribing across North Yorkshire and York.
- Palliative care team maintain responsibility for monitoring effect and need not the GP.
- Treated as a controlled drug.
- Would only ever be initiated and administered by palliative care team.

The APC used its guide on assigning RAG classification from Aug 2021 to agree the appropriate RAG status.

The APC approved the formulary application as a RED drug for painful wounds in palliative care where oral or IV opioids have failed. This was because requires specialist input to assess need for drug, assess benefit, and to administer the drug safely. Ready-made product is not easily available in primary care. Agreed that RED drug classification includes prescribing and use by Palliative Care team.

Noted that the decision fell within the delegated authority of the APC.

ACTION:

• JC/SAL to update the formulary websites.

PPI infusions in palliative care

The APC discussed the formulary application received for Omeprazole, Pantoprazole, Esomeprazole injection for subcutaneous infusion in palliative care. Omeprazole and pantoprazole injections are already on formulary for their licensed intravenous use. Esomeprazole would be an additional choice if a continuous syringe driver if required.

The following points were considered in reaching a decision:

- Choice of agent would depend upon location of patient i.e. in patient or community setting, whether it is necessary and practical to have a second syringe driver, Having more than one agent also allows flexibility if there are supply issues.
- In the past s/c ranitidine might have been considered but this is no longer available hence the need to consider using s.c proton pump inhibitors when the oral route is not possible and IV is not suitable.
- Unlicensed route of administration.
- PPIs cannot be mixed with any other drugs in the same syringe driver.
- May be availability issues in community pharmacy as listed as hospital only supply at wholesalers.
- Palliative care team maintain responsibility for monitoring effect and need not the GP.
- Would only ever be initiated and administered by palliative care team.
- Many of the patients requiring it would be inpatients within hospices.

The APC used its guide on assigning RAG classification from Aug 2021 to agree the appropriate RAG status.

The APC approved the formulary application as a RED drug because requires specialist input to assess need for drug, assess benefit, and to administer the drug safely. Injectable form of drug is also not readily available in primary care. Agreed that RED drug classification includes prescribing and use by Palliative Care team.

Noted that the decision fell within the delegated authority of the APC.

ACTION:

JC/SAL to update the formulary websites.

<u>Luforbec® inhaler</u>

The APC discussed the formulary application for Luforbec® inhaler. Requested for Asthma and COPD (note that the high strength 200/6 inhaler is only licensed for asthma) and to replace

Fostair® MDI on the formulary as cheaper.

The APC approved the application as a GREEN drug. The plan is for Luforbec® MDI to replace Fostair® MDI on the formulary and within the present treatment guidelines when an MDI is appropriate. There will be a continued focus to review existing patients on MDIs and to offer patients DPIs where appropriate.

Noted that the decision fell within the delegated authority of the APC.

ACTION:

JC/SAL to update the formulary websites.

16. Compassionate use/free of charge scheme requests Nil this month.

17. RMOC update

Nil this month.

Part 5 – Shared Care and Guidelines (non-mental health)

18. Valproate medicines for patients of child-bearing potential

In July 2022 NHS England published a national shared care protocol for valproate medicines for patients of child-bearing potential

In October 2022, RDTC, on behalf of Humber and North Yorkshire ICB started a consultation process, consulting on the implementation of the valproate medicines for patients of child-bearing potential national shared care protocol. The consultation was hosted via an open access website and was shared with all providers and stakeholders within Humber and North Yorkshire ICS and was open for feedback for six weeks, closing on 5th December 2022. The feedback was on the whole supportive of adopting the national shared care protocol for valproate medicines for patients of child-bearing potential, with a few caveats regarding specific patient circumstances.

In December 2022, MHRA released a statement regarding new safety measures for the initiation of valproate medicines. The new safety measures reference the requirement for two specialists to initiate valproate and the inclusion of males of childbearing age. To date – 21st February 2023 – the national shared care protocol has NOT been updated to reflect these new changes. NHSE advise the national advice and national shared care protocol will be updated in due course, and we are advised to follow the existing precautions, as set out in the existing shared care protocol – version July 2022.

Therefore, following due process, the APC was requested to approve the adoption of the existing (July 2022) shared care protocol valproate medicines for patients of child-bearing potential with Humber and North Yorkshire and APC logos.

This shared care protocol should be used for all existing patients. This protocol has been produced to support all prescribers who enter into shared responsibility arrangements to effectively manage the high risk of severe harm from valproate use.

The Humber and North Yorkshire shared care protocol for valproate medicines for patients of child-bearing potential will be updated accordingly, when the national shared care protocol for valproate medicines for patients of child-bearing potential is updated, to take into consideration the December 2022 MHRA guidance

Humber Medicines Management Team, North Yorkshire and York Medicines Management Team and Pharmacy teams within provider organisations will support the implementation of the shared care protocol, support when individual patients require a tailored approach to shared care and support to ensure that all female patients of childbearing age have an up-to-date pregnancy prevention programme in place.

The APC discussed and approved the adoption of the national shared care protocol (version July 2022) for valproate medicines for patients of child-bearing potential

ACTION:

- LA to circulate final approved version.
- JC/SAL to update the formulary websites.

19. Biologics Pathway for Axial Spondyloarthritis (Ankylosing Spondylitis) & Non-Radiographic Axial Spondyloarthritis

Updated version approved to include latest 30-day NICE TA for upadacitinib published in February 2023.

ACTION:

• JC/SAL to update the formulary websites.

Part 6 - Other Items of Business

20. Medicines committee and NTAG decisions - impact on North Yorkshire

A verbal update was given on changes to medicines decision making structures in the North East and North Cumbria which may impact on North Yorkshire. Some patients from North Yorkshire may be referred to South Tees or County Durham acute Trusts.

In the NENC all formulary decisions are now made by NTAG and not the APCs. The future and need for the three APCs in the NENC is currently under review. All NICE TA formulary decisions go out for consultation via the NTAG website for one month so North Yorkshire would be able to submit any comments/issues via this for consideration. Recognised the need to avoid postcode issues and ensure equity of access where possible.

NENC moving to single ICS formulary from April 2023 instead of the three existing APC formularies in the NENC.

It was agreed to add to the NENC Medicines Committee decision summaries to the NY&Y APC agenda each month as a standing agenda item under Part 7 of the agenda.

Part 7 – Standing Items (for information only)

21. IPMOC Minutes – January 2023

Circulated for information.

22. TEWV D&T Minutes - November 2022

Not yet available.

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

Not yet available.

24. Harrogate Trust Medicines and Therapeutics Group Minutes – since September 2022 Not yet available.

25. County Durham & Tees Valley APC Minutes – January 2023 Not yet available.

26. Yorkshire ICS APC Minutes – September and November 2022 Circulated for information.

27. Humber APC Minutes - February 2023

Circulated for information.

28. Humber APC Decisions & Recommendations - February 2023

Circulated for information.

29. RDTC Monthly Horizon scanning - February 2023

Circulated for information.

Any Other Business

Formulary applications received for April 2023 meeting

The APC the following formulary applications have been received to date for the April 2023 APC meeting:

- Dexcom ONE
- Buvidal® injection

Date and time of next meeting

Wednesday 5th April 2023, 2pm – 4.30pm, virtual meeting via Microsoft Teams