NHS
North Yorkshire and York
Area Prescribing Committee

North Yorkshire & York Area Prescribing Committee

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

Present

Name	Job Title	Organisation	Voting Member	Mar 2023	Apr 2023	May 2023	Jun 2023	Jul 2023
Ken Latta	Head of Medicines Optimisation	North Yorkshire Place	Y	Y	Y	Y	Y	Y
Dr Tim Rider	GP Prescribing Lead	North Yorkshire Place	Y	Y	Y	Y	Apols	Y
Laura Angus	Head of Medicines Optimisation and Interim Chief Pharmacist at Humber, & North Yorkshire ICS	City of York Place	Y	Y (from Item 15)	Fasial Majothi	Y	Y	Y (note Chris Ranson held voting rights)
Dr Shaun O'Connell	GP Lead for Acute Service Transformation	City of York Place	Y	Y	Apols	Apols	Apols	Apols
Dr William Ovenden	GP	City of York Place	Y	Y	Y	Apols	Y	Y
Kate Woodrow	Chief Pharmacist	Harrogate and District NHS Foundation Trust	Y	Apols	Y	Y	Sara Moore	Y
Dr Ben Walker (till Feb 2023)	Consultant and D&T Chair	Harrogate and District NHS Foundation Trust	Y	Victoria Millson	Victoria Millson	Apols	X	X
Stuart Parkes	Chief Pharmacist	York & Scarborough Teaching Hospitals NHS Foundation Trust	Y	Y	Jane Crewe	Y	Y	Y
Dr Chris Hayes	Consultant and D&T Chair	York & Scarborough Teaching Hospitals NHS Foundation Trust	Y	Y (from item 10)	Apols	X	X	Y (from i2.40pm)
Tracy Percival	Formulary Pharmacist	South Tees Hospitals NHS Foundation Trust	Y	Y	Y	Y	Y	Apols
Richard Morris	Deputy Chief Pharmacist	Tees, Esk and Wear Valleys NHS Foundation Trust	Y	Y	Apols	Y	Apols	Apols
Angela Hall	Public Health representative	North Yorkshire County Council	Y	Kurt Ramsden	Kurt Ramsden	Kurt Ramsden	Apols	Kurt Ramsden
Anita Dobson	Public Health representative	City of York Council	Y	Apols	Resigned			
Alison Levin	Finance representative	North Yorkshire Place	Y	Jo Horsfall	Apols	Jo Horsfall	Jo Horsfall	Jo Horsfall
Hazel Mitford	Lay/patient representative		Y	Apols	Apols	Y	Y	Y
Gavin Mankin (Professional Secretary)	Principal Pharmacist Medicines Management	Regional Drug & Therapeutics Centre, Newcastle	N	Y	Y	Y	Y	Y
Chris Ranson	Lead Medicines Management Pharmacist: Commissioning and Formulary	North Yorkshire Place	N	Y	Y	Y	Y	Y
Faisal Majothi	Medicines Optimisation Pharmacist	City of York Place	N	Y	See above	Y	Y	Apols
Jane Crewe	Formulary Pharmacist	York & Scarborough Teaching Hospitals NHS Foundation Trust	N	Y	See above	Y	Y	Y
Sara Abbas-Llewelyn / Emily Parkes	Formulary Pharmacist	Harrogate and District NHS Foundation Trust	N	X	Sara Abbas-Llewelyn	Sara Abbas-Llewelyn	Sara Abbas-Llewelyn	Sara Abbas-Llewelyn
Ian Dean	LPC Representative		N	Y	Y	Apols	Y	Apols
Dr Sally Tyrer	LMC Representative		N	X	X	Jane Raja	Jane Raja	
Sara Moore	Deputy Chief	Harrogate and District	N	Y	Y	Apols	See	Apols

	Pharmacist	NHS Foundation Trust					above	

The meeting was quorate with 9 out of 12 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 Tim Rider.

Part 1

1. Apologies for absence and quoracy check

Shaun O'Connell, Richard Morris, Tracy Percival, Sara Moore, Faisal Majothi, Ian Dean.

The APC noted that Laura Angus is now the ICB Chief Pharmacist for HNY and longer aligned to York. Therefore, she will no longer have voting rights at NY&Y APC; these will be transferred to another appropriate person when agreed. For today's meeting, Chris Ranson will deputise in terms of voting rights for the medicines optimisation representative from York.

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 on 7th June 2023

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

4. Outcome of items referred to June 2023 IPMOC

Nil referred and June 2023 IPMOC was cancelled.

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

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

AOB – Caverject® dual chamber supply issues, review of new product requests or proposed guidelines which include antimicrobial medicines, inclisiran, tertiary centre shared care.

6. Action log

<u>NY&Y APC terms of reference</u>
Updated APC Terms of Reference finalised and final version circulated. ITEM NOW CLOSED.

<u>New Drug Applications - Tranexamic acid nose drops</u>
YSFT have decided to no longer proceed with the application as no evidence available for long-term prophylactic use. ITEM NOW CLOSED.

<u>Formulary Updates approved at June 2023 APC</u>
JC/SAL have updated Y&S and Harrogate formularies. ITEM NOW CLOSED.

Outstanding actions from previous APC meetings

Bicalutamide RAG status
On today's agenda.

Diazoxide for chronic intractable hypoglycaemia
KW/SM/JC to develop shared care guideline to be presented to next APC for approval**.**

Medical Devices Commissioning and Formulary Position
RDTC currently reviewing previous MCC commissioning positions on individual medical devices and will circulate an updated draft for comment before presenting at September 2023 APC for approval.

Oral minoxidil for androgenic alopecia
ICB policy alignment group have confirmed they will review this particular policy across the ICB when the NICE TA for baricitinib is published. Agreed no further action for item for APC until this policy is reviewed by the ICB.

Guidelines for recognition and management of non-IgE cow's milk allergy in children – partial update
Additional wording to be added to the guideline now agreed with the author. This is so guideline is stronger to support GPs with clarity on when not to rechallenge. An updated guideline will come to the next APC for approval.

Dexcom ONE
Updated HNY CGM policy has now been approved and work on an implementation plan is ongoing. ITEM NOW CLOSED.

Hydroxychloroquine and chloroquine retinopathy: Recommendations on monitoring 16 December 2020 – updated RCOphth guidelines
Work on adopting national shared care template is ongoing in NY&Y.

Part 2 – Governance

7. Nil this month.

Part 3 – Mental Health

8. Melatonin SCG

The final version of the approved TEWN Melatonin SCG for NY&Y was circulated for information.
APC members suggested an amendment was needed to the indication "*Chronic sleep disturbance resulting in severe stress for the patient and/or family, in children and young people with the following conditions, where sleep hygiene measures have been insufficient"* to remove the word "or" and this will feedback to TEWV.
YSFT paediatricians have also raised some issues with melatonin being classed as shared care and the monitoring requirements. A paper will come to the next APC meeting.

Part 4 – Formulary issues

9. Appeals against previous APC decisions

None received.

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

- TA882: Voclosporin with mycophenolate mofetil for treating lupus nephritis
- TA885: Pembrolizumab plus chemotherapy with or without bevacizumab for persistent, recurrent or metastatic cervical cancer
- TA886: Olaparib for adjuvant treatment of BRCA mutation-positive HER2-negative high-risk early breast cancer after chemotherapy
- TA887: Olaparib for previously treated BRCA mutation-positive hormone-relapsed metastatic prostate cancer
- TA890: Difelikefalin for treating pruritus in people having haemodialysis
- TA891: Ibrutinib with venetoclax for untreated chronic lymphocytic leukaemia
- TA892: Mosunetuzumab for treating relapsed or refractory follicular lymphoma

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

- TA881: Ripretinib for treating advanced gastrointestinal stromal tumour after 3 or more treatments
- TA883: Tafasitamab with lenalidomide for treating relapsed or refractory diffuse large B-cell lymphoma

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

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

- TA884: Capmatinib for treating advanced non-small-cell lung cancer with MET exon 14 skipping (terminated appraisal)
- TA889: Ciltacabtagene autoleucel for treating relapsed or refractory multiple myeloma (terminated appraisal)

The drugs in the following TAs which are ICB-commissioned to be reflected in the formulary as RED drugs in the relevant chapters with links to the TAs:

- TA888: Risankizumab for previously treated moderately to severely active Crohn's disease. The potential cost impact in the future within the delegated authority of the APC.

NG18: Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update) - in May 2023, NICE reviewed the evidence on glucose-lowering agents for managing blood glucose levels in children and young people with type 2 diabetes. Updates include new or amended recommendations on:

- monitoring blood glucose levels (including real-time and intermittently-scanned continuous blood glucose monitoring) and reviewing treatment
- adding liraglutide, dulaglutide, or empagliflozin – currently not on local formularies for this indication.

The APC agreed these changes needed flagging to the ICB group who developed the CGM policy for consideration, plus to local paediatricians to arrive at a consensus on updating the formulary.

Medicines Safety MHRA Drug Safety Update – May 2023

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

ACTION:

- **JC/SAL to update the formulary websites.**
- **KL to flag to ICB need to review CGM policy in light of update to NICE NG18 around use in children and young people with type 2 diabetes.**
- **SP/KW to flag NICE NG18 updates re liraglutide, dulaglutide, or empagliflozin to arrive at a consensus on updating the formulary.**

11. Other formulary issues

Metolazone to replace xipamide

Confirmed post-May 2023 AOC that Xipamide has been discontinued. The expiry date of the last batch was May 2023.

Renal team at YSFT have five patients who were taking xipamide. Metolazone tends to be better at diuresis in lower renal function and can potentiate the action of loops so it would be the drug of choice for patients swapping from xipamide and new starters. BNF low dose and work towards requirement.

Heart failure Team at YSFT have about 10 patients prescribed xipamide over a year. Those on xipamide have already been switched onto bendroflumethiazide while waiting for metolazone to be approved. However, the patients are not managing as well on bendroflumethiazide. For new patients, because of cost, if add on diuretic is needed, teams will try bendroflumethiazide first-line and then only move to metolazone if not effective.

Xipamide was used on a PRN basis on top of IV furosemide in HF clinics and so is generally managed by the experienced HF nurses. There had been a few cases where patients responded well to xipamide and continued it as a regular medication (care home patient) monitored by a GP. However, this is rare.

At YSFT for all teams:

- The decision to treat with metolazone will either be made by the community heart failure team or by secondary care cardiologists or nephrologists. Treatment would normally be started at 2.5 mg/day and the dose must be adjusted according to the individual reaction of the patient.
- Monitoring (U&E, creatinine, weight, blood pressure and for signs of dehydration) by the initiating team at frequency decided on an individual patient basis. If a patient requires a low maintenance dose and it is the GP required to monitor, advice will be given on an individual patient basis.

The cardiologist at HDFT is advising just a straight swap to bendroflumethiazide.

The APC agreed to add metolazone to formulary as an AMBER SI drug as 2nd line alternative after bendroflumethiazide based on the feedback received from specialists. It noted the MHRA Drug Safety Update on differences in bioavailability between licensed metolazone and unlicensed metolazone, so prescribers need to be clear on prescription as to what is required.

ACTION:

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

Ferric maltol - review of RAG status

Ferric Maltol is currently on Y&S formulary as an AMBER SR drug below and is not listed on the Harrogate formulary.

Discussed and approved addition to Harrogate formulary as part of the formulary alignment at current RAG status – Amber SR.

The APC recommended that the prescribing information and flow chart on formulary is reviewed and, if necessary, updated by Gastroenterology and Cardiology, and at this point the prescribing advice could be relaunched and would support a review of the current RAG, with consideration given to changing to GREEN.

ACTION:

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

12. New Drug Applications

Tirbanibulin (Klisyri®▼, Almirall) 10 mg/g ointment

Requested for field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults.

It has equal efficacy to 5-fluorouracil and imiquimod. Offers advantage of short duration of therapy (5 days) which will improve compliance. In applicant's practice approximately 10 to 20%

of patients taking 5-fluorouracil do not complete the course due to the inflammatory reaction. This means that they go on to use a dermatology clinic slot. Imiquimod is also a long length of treatment and can occasionally cause systemic flulike illness and can exacerbate some pre-existing inflammatory diseases. Topical diclofenac is expensive, poor efficacy, very long duration of treatment (90 days).
The APC noted the costs compared to other options and concerns of cost impact in primary care if this replaced use of other options e.g. Efudix®, particularly as short duration of treatment will be very attractive to patients.
The APC was happy with the evidence base but before it could make a decision it wanted to know:

- Place in therapy and which product should be used when
- Will just secondary care prescribe this or is the expectation that primary care also prescribe

ACTION:

- **RDTC to confirm with applicant, place in therapy and which product should be used when, and will just secondary care prescribe this or is the expectation that primary care also prescribe.**

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

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

14. Shared care guidelines for approval
Nil this month.

15. Biologics Pathway for severe active Crohn's & moderate to severe Ulcerative Colitis – updated
The pathway has been updated to reflect the latest NICE guidance:

- NICE TA 888 - Risankizumab for previously treated moderately to severely active Crohn's disease
- NICE TA 905 - Upadacitinib for previously treated moderately to severely active Crohn's disease

Risankizumab requires the first 3 doses to be given as an IV infusion (anticipate 10 per year at Y&S) - Trust aware of day case impact on services. Thereafter, s/c homecare.
Upadacitinib is an additional oral option (ozanimod, filgotinib and tofacitinib other oral options).
The updated pathway was approved by the APC.

ACTION:

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

Part 6 – Other items of business

16. IQoro® medical device
The IQoro® medical device is available for prescribing and is listed in the drug tariff. YSFT have been approached by one of the Upper GI surgeons about the practicalities/possibility of prescribing IQoro® on the NHS for reflux management.
The promotional material lists it as:

- a treatment for reflux-based diseases as an alternative to long-term PPI medication or surgery
- for patients with dysphagia and other related conditions

The NICE Medtech briefings were presented to the APC. Key uncertainties around the evidence are the lack of high-quality, randomised studies and the unclear effect of IQoro® compared with

NHS standard care or spontaneous improvement.
The cost is £121.00 per device.

The APC agreed to that IQoro® should be classed as a BLACK drug based on the quality of evidence and uncertainties contained in the NICE Medtech briefings. Agreed that the evidence base is not sufficient to support a formulary application.

ACTION:

- **JC/SAL to update the formulary websites.**
- **RDTC to add to APC Medical Devices commissioning document.**

17. Prostate letters – Bicalutamide face-to-face and remote

The updated prostate letters – Bicalutamide face-to-face and remote consultation letters were presented to the APC. The 150 mg bicalutamide dose in combination with an LHRH analogue has now been removed.
The APC thought it had agreed previously that the GP should be asked to initiate both the bicalutamide and the LHRH analogue rather than secondary care starting the bicalutamide and expecting GP to start LHRH analogue within 7 days. These timescales will not work in primary care.
The APC discussed and agreed that a single letter was required to support the model of the GP starting both the bicalutamide and the LHRH analogue to ensure this can be properly and easily managed in primary care. The alternative is that secondary care initiates both the bicalutamide and the LHRH analogue. Priority is for the patient not to have injection therapy delayed.

ACTION:

- **JC to go back to urology to ask if single letter can be adopted or that secondary care initiate both the bicalutamide and the LHRH analogue. To also confirm if a two-week delay in starting bicalutamide is clinically significant and remove the word "immediately" from the letter to manage patient interactions with GP practice.**

18. Medicine Supply Notification: GLP-1 receptor agonists used in the management of type 2 diabetes - June 2023

APC noted the recently issued medicines supply notification for GLP-1 receptor agonists used in the management of type 2 diabetes.

Part 7 – Standing items (for information only)

19. IPMOC minutes – May 2023

Not yet available.

20. TEWV D&T minutes – March 2023

Not yet available.

21. York & Scarborough Trust Drug and Therapeutics Committee minutes – March 2023

Circulated for information.

22. Harrogate Trust Medicines and Therapeutics Group minutes – since September 2022

Not yet available.

23. West Yorkshire ICS APC Minutes – since March 2023

Not yet available.

24. Humber APC minutes – May 2023

Circulated for information.

25. Humber APC decisions & recommendations – May 2023
Circulated for information.

26. RDTC Monthly Horizon scanning – June 2023
Circulated for information.

27. NENC Medicines Committee decision Summary – June 2023
Circulated for information.

Any Other Business

Caverject® dual chamber supply issues
Seems there is a supply issue with Caverject® dual chamber and GPs are starting to prescribe Viridal Duo. Pfizer have said that Caverject® dual chamber will not be produced until 2024. Primary care already using Viridal Duo instead and secondary care will do the same.

Review of new product requests or proposed guidelines which include antimicrobial medicines
The newly formed HNY ICS Antimicrobial Stewardship Steering Group proposed that any new product requests or new guidelines which include antimicrobial medicines are sent to them for screening, prior to APC review. This will enable the local microbiologists and antimicrobial pharmacists in our ICS geography to debate and discuss the merits (or otherwise) of such new requests as a peer group. A specialist opinion would then be submitted by the HNY ICS Antimicrobial Stewardship Steering Group to each of the two APCs in a timely manner. This would not replace APC debate but add context and specialist opinion to fully inform the decision-making process of the APCs.
This process was supported by the APC.

Inclisiran
Ongoing issues with GPs refusing to prescribe inclisiran were discussed. Note that locally an update to the shared care LES is being considered to include funding for GPs to administer inclisiran.

Morphine 100 microgram/ml oral solution overdose
The APC noted the NHS England North East & Yorkshire Serious Incident Case Study:
Infant Morphine Overdose Investigation Summary & Learning July 2023. The necessary actions are currently being worked through locally in primary and secondary care.
Both the York and Harrogate formularies list as a RED drug.

Formulary applications received for August 2023 meeting
The APC have received the following formulary applications to date for the July 2023 APC meeting:

- Nil to date.

Date and time of next meeting
Wednesday 2nd August 2023, 2pm – 4.30pm, virtual meeting via Microsoft Teams