

North Yorkshire & York Area Prescribing Committee

Wednesday 6th December 2023 2pm – 4pm, virtual meeting via Microsoft Teams

Present

Name	Job Title	Organisation	Voting Member	Jul 2023	Aug 23	Sep 2023	Oct 2023	Dec 2023
Ken Latta	Head of Medicines Optimisation	North Yorkshire Place	Y	Y	Apols	Y	Y	Y
Dr Tim Rider	GP Prescribing Lead	North Yorkshire Place	Y	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	Y (note Chris Ranson held voting rights)	Y (note Chris Ranson held voting rights)	Y (note Chris Ranson held voting rights)	From 3.25pm (note Chris Ranson held voting rights)	From 3.36pm (note Chris Ranson held voting rights)
Dr Shaun O'Connell	GP Lead for Acute Service Transformation	City of York Place	Y	Apols	Apols	Apols	Apols	Resigned
Dr William Ovenden	GP	City of York Place	Υ	Υ	Υ	Apols	Υ	Υ
Kate Woodrow	Chief Pharmacist	Harrogate and District NHS Foundation Trust	Y	Y	Apols	Y	Sara Moore	Apol
Dr Joanna Cunnington (from Sep 2023)	Consultant and D&T Chair	Harrogate and District NHS Foundation Trust	Y	Х	Х	Y	Y	Y
Stuart Parkes	Chief Pharmacist	York & Scarborough Teaching Hospitals NHS Foundation Trust	Y	Y	Y	Apols (note Jane Crewe held voting rights)	Y	Y
Dr Chris Hayes	Consultant and D&T Chair	York & Scarborough Teaching Hospitals NHS Foundation Trust	Y	Y (from 2.40pm)	Y (from 2.25pm)	Y	Х	Х
Tracy Percival	Formulary Pharmacist	South Tees Hospitals NHS Foundation Trust	Y	Apols	Y	Y	Apols	Y
Richard Morris	Deputy Chief Pharmacist	Tees, Esk and Wear Valleys NHS Foundation Trust	Y	Apols	Chris Williams	Y	From 3.30pm	Until 3.08pm
Angela Hall	Public Health representative	North Yorkshire County Council	Y	Kurt Ramsden	Kurt Ramsden	Apols	Kurt Ramsden	Kurt Ramsden
Alison Levin	Finance representative	North Yorkshire Place	Y	Jo Horsfall	Jo Horsfall	Apols	Jo Horsfall	Jo Horsfall
Hazel Mitford	Lay/patient representative		Y	Y	Y	Y	Y	X
Gavin Mankin (Professional Secretary)	Principal Pharmacist Medicines Management	Regional Drug & Therapeutics Centre, Newcastle	N	Y	Dan Newsome	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	Apols	Y	Apols	Y	Y
Jane Crewe	Formulary Pharmacist	York & Scarborough Teaching Hospitals NHS Foundation Trust	N	Y	Y	Y	Y	Y
Sara Abbas-	Formulary Pharmacist	Harrogate and District NHS	N	Sara	Apols	Apols	Apols	Apols

Llewelyn		Foundation Trust		Abbas- Llewelyn				
Ian Dean	LPC Representative		N	Apols	Υ	Υ	Apols	Υ
Dr Jane Raja	LMC Representative		N	Y	Y	Y	Y	Υ
Sara Moore	Deputy Chief Pharmacist	Harrogate and District NHS Foundation Trust	N	Apols	Y (2.15pm)	Y	Y	Apols

The meeting was quorate with 9 out of 14 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.

The meeting noted that following his return to work and a restructure within the ICB during his absence that Shaun O'Connell has stepped down from the NY&Y APC as he no longer has role in prescribing. The APC wished to express its thanks to Shaun for his contributions and commitment to the APC since its creation plus the Y&S MCC before that.

Part 1

1. Apologies for absence and quoracy check

Kate Woodrow. Sara Moore

The meeting was quorate.

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 4th October 2023

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

4. Outcome of items referred to September and October 2023 IPMOC

TA902: Dapagliflozin for HFpEF

Above the current threshold for Place / IPMOC approval. Approved at 14th Nov 2023 ICB Exec meeting.

TA906: Rimegepant for migraine

Above the current threshold for Place / IPMOC approval. Approved at 14th Nov 2023 ICB Exec meeting.

TA875: Semaglutide for managing overweight and obesity

Expected costs have been modelled and will be presented to ICB Executive Board in early 2024. The need to consider both commissioning arrangements and drug costs was recognised for any future ICB-wide implementation. Noted that current provision in Humber Place is via a community provider service. For update January 2024.

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

Nil matters arising not on the agenda.

AOB: NY&Y Vitamin D guidelines – updated reference ranges, and ferric maltol/oral iron guidelines.

6. Action log

TA 875: Semaglutide for managing overweight and obesity

Update as above. Referred to October 2023 IPMOC as above the level of delegated authority of the APC.

New Drug Applications - Modafinil for fatigue associated with MS

On today's agenda.

Formulary Updates Approved at Oct 2023 APC

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

ADHD drug current supply issues

NY&Y MO Team to work with TEWV on some comms to go out to primary care in NY&Y by the end of week ending 6th October 2023, Confirmed action completed. ITEM NOW CLOSED.

Outstanding actions from previous APC meetings

Diazoxide for chronic intractable hypoglycaemia

On today's agenda.

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.

NG18: Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update) - May 2023

SP/KW have flagged NICE NG18 updates re liraglutide, dulaglutide, or empagliflozin to arrive a consensus on updating the formulary. YSFT would not expect to manage these patients. In HDFT all NICE updates picked up via Directorates and the Trust Clinical Effectiveness Forum and NICE compliance declared. Note supply problems with these medicines, so no new initiations. ITEM NOW CLOSED.

Prostate letters - Bicalutamide face to face and remote

On today's agenda.

Melatonin prescribing paper

NY MO team still to complete paper to submit to future APC outlining the current issues with melatonin prescribing for consideration alongside the request to change the status.

TA902: Dapagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction.

An updated HF guidance to support transfer of prescribing into primary care was presented to and approved by the APC subject to:

- Logos be updated to NY&Y APC logo
- Improve clarity around boxes at top in the "Prevent" row

<u>Hydroxychloroquine and chloroquine retinopathy: Recommendations on monitoring 16</u> 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. TEWV D&T committee summary - 23rd November 2023

Circulated for information.

9. Clozapine: supporting guidance for primary care

An information sheet about clozapine has been available from TEWV to primary care partners for a number of years. Recently, CNTW FT has produced a similar document, and as part of NENC ICB harmonisation, TEWV was invited to comment on it. In doing so, TEWV agreed to adopt the CNTW format as the NENC ICB version. TEWV needs to continue to provide supporting information on clozapine to primary care partners within its footprint that are part of HNY ICB. This could either be the current TEWV version, or a re-badged NENC ICB version. The purpose of this paper is to seek the APCs preference. TEWV preference would be to adopt the NENC version so that only one set of content needs to be reviewed Trustwide moving forward.

The APC agreed to adopt the NENC version across NY&Y.

Part 4 – Formulary issues

10. Appeals against previous APC decisions

<u>Modafinil for fatigue in MS – request to reconsider traffic light classification and follow up from October 2023 meeting</u>

At the October 2023 APC meeting, modafinil for fatigue in MS was discussed and approved with a RED Hospital only position agreed. APC now asked to reconsider with a view to approving as Amber shared care agreement. Applicant was also asked to provide clarification as to what the formulary position was at South Tees and this has now been confirmed.

NICE NG 220 MS in Adults- management suggests that once established on a stable dose, ongoing prescribing may be under shared care arrangements.

1.5.16 When the person with MS is on a stable dose of a medicine for fatigue, subsequent prescriptions may be issued by another prescriber as part of a shared-care agreement under the direction of the initiating specialist prescriber.

Modafinil is already classed as Amber shared care for excessive daytime sleepiness in Parkinson's disease, with the elderly population being more high risk for cardiovascular risk than the potentially younger MS population.

The formulary position of neighbouring Trusts is described below as was requested at the October meeting. However, all stated that their formulary positions have not been reviewed since NICE NG220 was published last year. Applicant wishes to adopt the NICE approved approach to prescribe under shared care agreement, which would be consistent with that taken by Leeds and our current precedent for the treatment of excessive sleepiness in PD. Also feel that a decision should not be unduly influenced by the practice of other hospitals who have not reviewed their formulary position since the NICE guidance was issued.

The APC discussed and approved a change from RED to AMBER SC as an option per NICE guidance for fatigue associated with Multiple Sclerosis. This is an unlicensed indication and matches status for us in Parkinsons disease which is also unlicensed and recommended by NICE. The applicant was also asked to address the following points:

 Why is there a difference of opinion of use of modafinil between specialists at YSFT and HDFT?

- Initial/baseline monitoring should be done by the specialist and not the GP.
- Min 8 weeks supply initially from secondary care and there must be a clinical response to treatment for the modafinil to be continued.

ACTION:

- JC/SAL to update the formulary websites.
- JC to update existing modafinil shared care guideline.
- JC/SAL to discuss why is there a difference of opinion of use of modafinil between specialists at YSFT and HDFT.

11. Formulary NICE TAs and MHRA Drug Safety Update - September and October 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:

- TA913: Mavacamten for treating symptomatic obstructive hypertrophic cardiomyopathy
- TA914: Pembrolizumab for previously treated endometrial, biliary, colorectal, gastric or small intestine cancer with high microsatellite instability or mismatch repair deficiency
- TA915: Pegunigalsidase alfa for treating Fabry disease
- TA917: Daratumumab with lenalidomide and dexamethasone for untreated multiple myeloma when a stem cell transplant is unsuitable
- TA921: Ruxolitinib for treating polycythaemia vera
- TA927: Glofitamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments

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:

• TA923: Tabelecleucel for treating post-transplant lymphoproliferative disorder caused by the Epstein-Barr virus (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:

- TA916: Bimekizumab for treating active psoriatic arthritis
- TA918: Bimekizumab for treating axial spondyloarthritis
- TA920: Tofacitinib for treating active ankylosing spondylitis
- TA925: Mirikizumab for treating moderately to severely active ulcerative colitis

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

- TA919: Rimegepant for treating migraine
- TA922: Daridorexant for treating long-term insomnia Referred to IPMOC due to financial/commissioning impact. Need to ensure CBTi service commissioned and available across HNY.
- TA924: Tirzepatide for treating type 2 diabetes (GREEN drug for 2.5mg and 5mg doses, and AMBER SR ASR for doses greater than 5mg) - Referred to IPMOC due to financial impact.

Medicines Safety MHRA Drug Safety Update - September and October 2023

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

ACTION:

JC/SAL to update the formulary websites.

12. Other formulary issues

MSK chapter alignment/ review

The APC approved the proposed alignment of the MSK formulary chapter in NY&Y.

ACTION:

JC/SAL to update the formulary websites.

Blood and nutrition chapter alignment/ review

The APC approved the proposed alignment of the Blood and nutrition formulary chapter in NY&Y.

ACTION:

JC/SAL to update the formulary websites.

Anastrozole for primary prevention of breast cancer

The national multi-agency Medicines Repurposing Programme successfully secured a MHRA licence variation for anastrozole on 6 November 2013 for this indication.

Anastrozole's marketing authorisation now includes a new indication of primary prevention of breast cancer in postmenopausal women at moderate or high risk. The new indication mirrors the pre-existing NICE guideline recommendation. The NICE guideline on familial breast cancer has recommended anastrozole off-label since 2017. The NICE guideline has been updated to reflect that anastrozole is now licensed for prevention.

Locally GPs have been initiated on advice of a specialists usually the clinical genetics service. APC therefore agreed should be included on the formulary as AMBER SR for this indication.

ACTION:

JC/SAL to update the formulary websites.

13. New Drug Applications

Nil this month.

14. Compassionate use/free of charge scheme requests

Nil this month.

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

15. Shared care guidelines for approval

Diazoxide shared care

New shared care guidelines for Diazoxide were presented to the APC. HDFT have now been consulted on the content.

Diazoxide for treating intractable hypoglycaemia in adults was approved as an AMBER SC drug in November 2022. Less than 5 patients per year expected across North Yorkshire & York.

A number of concerns were expressed by the APC which meant the APC could not approve the SCG presented to it:

- Some felt does not fit a drug suitable for shared care as condition is so rare.
- If monitoring us required to prescribe the drug then same person should have responsibility for both prescribing and monitoring. It is not shared care if specialist does monitoring and GP only prescribes.
- Potential for confusion in the what the draft SCG is written has to do who does monitoring is it done by GPs or not done by GPs.
- Concerns that dose titration/modifications not generally responsibility of GP under shared care. GPs usually only prescribe shared care drugs once the dose is stable.

YSFT indicated that generally they will continue to retain both prescribing and monitoring in secondary care for this drug for this indication.

ACTION:

 JC to discuss concerns raised by APC with SM and report back to next APC meeting.

16. NY&Y diabetes pathway updated with tirzepatide

An updated type 2 diabetes pathway to include tirzepatide was presented to and approved by the APC subject to tirzepatide being added to pages 2 and 4. Noted that needs to be referred to IPMOC for final approval due to financial impact. Agreed to recommend that be classed as a GREEN drug for 2.5mg and 5mg doses, and AMBER SR ASR for doses greater than 5mg.

ACTION:

• JC/SAL to update the formulary websites.

17. HDFT Fragility Fracture – Secondary prevention Guidelines – update

The update of this guideline has involved minor changes to spelling and clarity of wording of certain statements. This guideline is intended for inpatient care. Noted that YSFT have been consulted.

The updated version was approved by the APC for adoption across NY&Y subject to:

- Link to NY&Y Vitamin D Guidelines needs updating.
- Update logo to NY&Y APC logo to allow for use across NY&Y.
- Confirm that final two boxes on right of guideline do not duplicate themselves re teriparatide and romosozumab.

ACTION:

- SM to arrange for final version of guideline to be produced/circulated.
- JC/SAL to update the formulary websites.

18. HDFT Osteoporosis Guidelines – Full version and Flow chart – update

In light of the new NOGG guidance for Osteoporosis HDFT have updated their Trust Osteoporosis Guidelines Updated included simplified risk factor section and updated the treatment options in line with NOGG. Have included Romosozumab, a new anabolic treatment now available and approved for use by NICE. Romosozumab has been approved separately by the APC as per its current NICE TA. Noted that YSFT have been consulted.

The updated version was approved by the APC for adoption across NY&Y subject to:

- Update logo to NY&Y APC logo to allow for use across NY&Y.
- Roadtesting by a GP (WO) in primary care before coming back to February 2024 APC for final sign off.

ACTION:

- WO to roadtest updated guideline in primary care before it comes back to February 2024 APC for final sign off.
- SM to arrange for final version of guideline to be produced/circulated.

19. Psoriatic arthritis biologics pathway – update to reflect TA916

An updated pathway was presented to and approved by the APC.

ACTION:

- JC/SAL to update the formulary websites.
- 20. Biologics Pathway for Axial Spondyloarthritis (Ankylosing Spondylitis) & Non-Radiographic Axial Spondyloarthritis update to reflect TA918 and TA920

An updated pathway was presented to and approved by the APC.

ACTION:

JC/SAL to update the formulary websites.

21. Ulcerative colitis biologics pathway - update to reflect TA925

An updated pathway was presented to and approved by the APC.

ACTION:

JC/SAL to update the formulary websites.

22. YSFT Bicalutamide/LHRH analogue letter to GPs

The final YSFT Bicalutamide/LHRH analogue letter to GPs was approved by the APC. This applies to YSFT only and not to HDFT.

Part 6 - Other items of business

23. Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients

The APC received the National Patient Safety Alert published on the 28th November 2023 for information. The APC noted that this was being picked by the ICB Quality & Safety Group chaired by Laura Angus.

Part 7 – Standing items (for information only)

25. IPMOC minutes - September 2023

Circulated for information.

26. TEWV D&T minutes - March, May, July and September 2023

Circulated for information.

- 27. York & Scarborough Trust Drug and Therapeutics Committee minutes since July 2023 Not yet available.
- 28. Harrogate Trust Medicines and Therapeutics Group minutes since September 2022
 Not yet available.
- 29. West Yorkshire ICS APC Minutes since March 2023 Not vet available.

rior you available.

30. Humber APC minutes - October 2023

Circulated for information.

31. Humber APC decisions & recommendations – October and November 2023

Circulated for information.

32. RDTC Monthly Horizon scanning – October and November 2023

Circulated for information.

33. NENC Medicines Committee decision Summary – September and October 2023

Circulated for information.

Any Other Business

NY&Y Vitamin D guidelines - updated with new reference ranges

In their most recent update to their vitamin D guidelines the Royal Osteoporosis Society amended the vitamin D treatment thresholds. Following review of the Scientific Advisory Committee on Nutrition (SACN) and Institute of Medicine (IOM) reports, we propose that the following vitamin D thresholds are adopted by UK practitioners in respect to bone health:

– plasma 25(OH)D < 25 nmol/L is deficient

- plasma 25(OH)D of 25-50 nmol/L may be inadequate in some people
- plasma 25(OH)D > 50 nmol/L is sufficient for almost the whole population.

NICE CKS also quotes 25nmol/L.

The APC agreed to update NY&Y vitamin D guidelines with the latest national reference ranges. This will have minimal or no cost impact. Fewer people will fall into the range of being classed as deficient (as there will be a lower cut off) and would therefore definitely require treatment irrespective of any other factors (such as fragility fracture/osteoporosis/high fracture risk, etc.)

Ferric maltol/oral iron

In July 2023 the NY&Y APC reviewed the RAG status of ferric maltol. 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. This has subsequently accidently been missed off the NY&Y APC Action Log as an action for the NY&Y Medicines Management Team. Agreed that KL/JC would discuss this outside of the APC meeting and agreed who was taking this action forward.

Date and time of next meeting

Wednesday 7th February 2024, 2pm – 4.30pm, virtual meeting via Microsoft Teams (January 2024 meeting cancelled due to Junior Doctor's Strike, NICE Tas published in Nov/Dec 2023 to be dealt with via email)