

North Yorkshire & York Area Prescribing Committee

Wednesday 6th October 2021
 2pm – 4.30pm, virtual meeting via Microsoft Teams

Present

Name	Job Title	Organisation	Jul 2021	Aug 2021	Sep 2021	Oct 2021
Ken Latta	Head of Medicines Optimisation	North Yorkshire CCG	Y	Y	Rachel Ainger	Y
Dr Tim Rider	GP Prescribing Lead	North Yorkshire CCG	Y	Y	Y	Apols
TBC	GP	North Yorkshire CCG	X	X	X	X
Laura Angus	Head of Medicines Optimisation	Vale of York CCG	Y	Apols	Faisal Majothi	Y (from 14.40)
Dr Shaun O'Connell	GP Lead for Acute Service Transformation	Vale of York CCG	Y	Y	Apols	Apols
Dr William Ovenden	GP	Vale of York CCG	Apols	Y	Y	Y
Kate Woodrow	Chief Pharmacist	Harrogate and District NHS Foundation Trust	Y	Y	Sara Moore	Y
Dr Ben Walker	Consultant and D&T Chair	Harrogate and District NHS Foundation Trust	Y	Y	Y	Y
Dr S Brotheridge	Consultant	Harrogate and District NHS Foundation Trust	X	Apols	Apols	X
Stuart Parkes	Chief Pharmacist	York Teaching Hospitals NHS Foundation Trust	Y	Kirsten Evans	Y	Y
Dr Peter Hall	Consultant and D&T Chair	York Teaching Hospitals NHS Foundation Trust	Apols	Y	Apols	Y
Dr Chris Hayes	Consultant	York Teaching Hospitals NHS Foundation Trust	Y	X	X	X
Tracy Percival	Formulary Pharmacist	South Tees Hospitals NHS Foundation Trust	Y	Y	Y	Y
	Consultant	South Tees Hospitals NHS Foundation Trust	X	X	X	X
Richard Morris	Deputy Chief Pharmacist	Tees, Esk and Wear Valleys NHS Foundation Trust	Y	Chris Williams	Y	Apols
Shona McIlrae	Consultant Psychiatrist	Tees, Esk and Wear Valleys NHS Foundation Trust	Apols	Apols	X	X
Angela Hall	Public Health representative	North Yorkshire County Council	Y (till 4.30pm)	Hira Singh	Y	Y
Anita Dobson	Public Health representative	City of York Council	Apols	Y	Y	Y
Alison Levin	Finance representative	North Yorkshire CCG	Y (till 4.45pm)	Kathryn Shaw-Wright	Y	Kathryn Shaw-Wright
Steve Jordan	Contracting representative	North Yorkshire CCG	Y (till 4.30pm)	X	Y	Apols
Hazel Mitford	Lay/patient representative		Y	Y	Y	Y
In attendance (non-voting membership):						
Gavin Mankin (Professional Secretary)	Principal Pharmacist Medicines Management	Regional Drug & Therapeutics Centre, Newcastle	Y	Y	Y	Y
Chris Ranson	Lead Medicines Management Pharmacist: Commissioning and Formulary	North Yorkshire CCG	Y	Rachel Ainger	Y	Y
Faisal Majothi / Jamal Hussain	Medicines Optimisation Pharmacist	Vale of York CCG	Y	Y	See above	Faisal Majothi
Jane Crewe	Formulary Pharmacist	York Teaching Hospitals NHS Foundation Trust	Y	Y	Y	Y

Sara Abbas-Llewelyn / Emily Parkes	Formulary Pharmacist	Harrogate and District NHS Foundation Trust	X	X	X	X
Ian Dean	LPC Representative		Y (till 4.30pm)	Y (till 3pm)	Y (till 3pm)	Apols
Dr Sally Tyrer	LMC Representative		Apols	Y (till 3pm)	Y (till 3pm)	Apols
Sara Moore	Deputy Chief Pharmacist	Harrogate and District NHS Foundation Trust	Y (till 4pm)	X	See above	X
Chris Williams	Chief Pharmacist	Tees, Esk and Wear Valleys NHS Foundation Trust	Y	See above	X	Apols

In attendance

Emily Brown (RDTC) – to facilitate sharing of papers on MS Teams

The meeting was quorate with 12 out of 19 currently appointed voting members in attendance.

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 Stuart Parkes.

Part 1

1. Apologies for absence and Quoracy Check

Shaun O'Connell, Richard Morris, Chris Williams, Tim Rider, Steve Jordan, Ian Dean, Sally Tyrer

2. Declarations of Interest

Members were reminded to complete and return the declarations of interest form that was circulated after the July 2021 APC meeting.

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:

None declared

3. Minutes of Previous APC & Decision Summary of Meeting Held 1st September 2021 (+outcome of VoY CCG exec)

The minutes of the September 2021 APC were approved as true and accurate record.

It was noted that the VoY CCG CE committee has approved the recommendations from the September 2021 APC Meeting.

4. Matters Arising Not On The Agenda & Declarations of AOB

Prescribing guidance for ocular surface diseases, including dry eye

The APC noted that minor amendments have been made to the pathway approved at the September 2021 APC to reflect AMBER SI formulary status of Ilube, Ikevis, and Sodium chloride 5% eye drops.

5. **Action Log**

TEWV Dosulepin, Promazine and Trimipramine Deprescribing Guideline

Trusts and CCGs have shared bulletin within their organisations to raise awareness. ITEW NOW CLOSED.

TEWV Memo Haloperidol 500 micrograms tablets cost increase

Trusts and CCGs have shared bulletin within their organisations to raise awareness. ITEM NOW CLOSED.

JEC has raised awareness with St Leonards's Hospice and discussed alternatives in palliative care which are limited. ITEM NOW CLOSED.

Formulary NICE TAs and MHRA Drug Safety Update – August 2021 plus Mycophenolate for autoimmune hepatitis and Infliximab for PRP, Dry eye guideline, Peristeen TAI

JC/ABS have updated the formulary websites with the approved changes now approved by VoY CCG. ITEM NOW CLOSED.

Grass Pollen Extract (Grazax®) Formulary Application

On today's agenda for approval.

HRT Guidelines

Final draft on today's agenda for approval.

Gastrointestinal Formulary Review

Y&S Formulary still to be updated with changes but Harrogate formulary now updated.

Outstanding Actions from Previous APC Meetings

Formulary NICE TAs and MHRA Drug Safety Update – June 2021

JC/ABS have updated the formulary websites with the approved changes now approved by VoY CCG. ITEM NOW CLOSED.

Psoriatic arthritis pathway

Version control has been added and the formulary websites have been updated with link to pathway. ITEM NOW CLOSED.

APC Terms of Reference Including Governance Arrangements

Have now been approved by NY CCG. ITEM NOW CLOSED.

Formulary NICE TAs and MHRA Drug Safety Update – July 2021 incl indapamide MR + Estring

JC/ABS have updated the formulary websites with the approved changes now approved by VoY CCG. ITEM NOW CLOSED.

Bempedoic acid

Updated local lipid management pathway to included bempedoic acid on today's agenda.

Biologics pathway for moderate rheumatoid arthritis

JC/ABS have updated the formulary websites with link to pathway. ITEM NOW CLOSED.

Biologics pathway for Axial Spondyloarthritis and non-radiographic axial spondyloarthritis (updated)

JC/ABS have updated the formulary websites with link to pathway. ITEM NOW CLOSED.

National Patient Safety Alert - Inappropriate anticoagulation of patients with a mechanical heart valve

KL reported that alert was distributed to GP practices but GP practices not asked to confirm compliance. CCG medicines safety group will come back to APC if any issues arise. ITEM NOW CLOSED.

Liraglutide for Obesity

KL/TR to follow up commissioning of a Tier 3 weight management service and compliance with NICE TA on liraglutide for obesity within NY CCG – still in progress..

SOC to follow up commissioning of a Tier 3 weight management service and compliance with NICE TA on liraglutide for obesity within VoY CCG

– no update available for this meeting.

Historic Actions Carried Over from June 2021 MCC meeting

Oilatum Plus – appeal

Still in progress within YFT.

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

Awaiting final guidance and SCG template from RMOC. Locally looking to have required ophthalmology screening service in place for when national SCG is published. Verbal update on discussion around local service provision was given to the APC. HDFT have an ophthalmology screening service being set up and discussions ongoing with YFT and STHFT. Any business cases for setting up the required ophthalmology screening service need to go to CCG Finance & Contracting for approval.

Melatonin YFT Shared care

On hold pending outcome of local working group on prescribing issues around melatonin.

Part 2 – Governance

6. Nil this month.

Part 3 – Mental Health

7. Nil this month.

Part 4 – Formulary Issues

8. Appeals Against Previous APC Decisions

None received.

9. Formulary NICE TAs and MHRA Drug Safety Update – September 2021

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

- TA725: Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy
- TA728: Midostaurin for treating advanced systemic mastocytosis
- TA729: Sapropterin for treating hyperphenylalaninaemia in phenylketonuria

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:

- TA724: Nivolumab with ipilimumab and chemotherapy for untreated metastatic non-small-cell lung cancer
- TA726: Daratumumab with pomalidomide and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal)
- TA727: Isatuximab with carfilzomib and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal)

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

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

- TA723: Bimekizumab for treating moderate to severe plaque psoriasis

Medicines Safety (MHRA drug safety update – September 2021)

The group noted the drug safety updates for September 2021. The links are to be added to the relevant sections of the formulary.

ACTION:

- **JC/ABS to update the formulary websites once approved by VoY CCG.**

10. Other Formulary Issues

Bempedoic acid

A NY&Y Bempedoic acid in management of hyperlipidemia guideline, including a lipid pathway for primary care was presented to the APC.

After discussion it was agreed that the pathway required further work before it could be approved. This was because:

- NICE guidance as it stands states that bempedoic acid should not be used concurrently with a statin and specifically states “NICE was not able to evaluate the use of bempedoic acid plus ezetimibe with low intensity statins when higher intensity statins are not tolerated.
- Pathway requires something more specific on the use of statins and maximizing their use/dose before progressing to other treatment options.
- Pathway also needs updating to include inclisiran.

Discussion also took place on the need for a local pathway and if the national AAC Lipid Pathway and ACC Statin Intolerance Pathway could not be adopted locally instead.

The APC agreed to approve the addition to the formulary of Bempedoic acid as a GREEN drug as per the NICE TA, and that not to be used in combination with statins as this is not supported by the NICE TA.

ACTION:

- **JC/ABS to update the formulary websites once approved by VoY CCG.**
- **JEC to seek further clarify around interpretation of NICE TA and also if ACC Lipid Pathway and ACC Statin Intolerance Pathway could be adopted locally.**

Inclisiran

The APC discussed that the NICE TA published on the 6th October 2021 Inclisiran is recommended as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults.

It is recommended only if:

- There is a history of any of the following cardiovascular events:
 - Acute coronary syndrome (such as myocardial infarction or unstable angina needing hospitalisation),
 - Coronary or other arterial revascularisation procedures
 - Coronary heart disease
 - Ischaemic stroke or
 - Peripheral arterial disease, and
- Low density lipoprotein cholesterol (LDL-C) concentrations are persistently 2.6 mmol/l or more, despite maximum tolerated lipid lowering therapy.

Routine funding of inclisiran is to be available within 30-days of the publication of the NICE TA.

The APC noted the national mandate and push for APCs to add this to formularies as a GREEN drug. However, APC members expressed concerns about the apparent lack of side-effects, lack of long term safety data, and lack of cardiovascular outcome data. Clinical data to date is based in a surrogate marker of outcome.

The Accelerated Access Collaborative and Academic Health Science Networks are working will to support the implementation of inclisiran within a primary care setting. NHS Digital are developing a case finding tool / business rule set for integration into GP systems, e.g. EMIS. This aims to be live in the autumn and will create 'in-session alerts' to support patient identification for secondary prevention of ASCVD at GP practice level. The AAC Lipid Management Pathway is also in the process of being updated to include Inclisiran. Place in therapy likely to be before referral to specialists for a PCSK-9 inhibitor.

The NHS will fund inclisiran centrally from a national NHS budget in order that local finances are not a barrier to the local uptake of inclisiran. To enable primary care providers (GP surgeries or pharmacies) to be able to purchase inclisiran directly from the national wholesaler for the medicine, a 'nominal' price (charge) has been agreed at which local primary care providers will be able to purchase the medicine.

Inclisiran will be available in primary care as a personally administered item via an FP34D form or on an FP10 prescription, and will be listed in the Drug Tariff at a reimbursed price of £55 per injection. After an initial dose and another at 3 months, inclisiran is maintained by two doses a year by subcutaneous injection.

It is expected locally that following approval the introduction of inclisiran into clinical practice will be gradual. The APC also agreed for the need for statin therapy to be maximized before progressing to this agent.

The APC felt that primary care was the right place for this drug to be prescribed and administered. This is because more it is expensive to give in secondary care, and these patients are generally managed in primary care.

The APC approved approve adding Inclisiran to the formulary as a GREEN drug as per NICE TA and NHSE Medicines Optimisation Team Briefing. However a holding statement will be issued to primary care that not to be prescribed until supporting lipid pathway and AHSN/AAC toolkit for primary care to support roll out in place. It was noted that due to potential costs this decision requires final approval from both CCGs as cost impact above the delegated authority of the APC.

ACTION:

- **JC/ABS to update the formulary websites once approved by VoY and NY CCG.**

11. New Drug Applications

Grass Pollen Extract (Grazax®)

The submission for Grazax was discussed at the last APC meeting and the committee asked for additional information/ reassurance on a number of points:

1. *Follow up / monitoring of patients to ensure there was a clear benefit*
Review visits confirmed from local guidance as
 - Review regularly whilst on treatment generally in September/October
 - Repeat allergic rhino-conjunctivitis (ARC) assessment score
 - Discuss issues with treatment & concerns
 - Further review in 2nd & 3rd year with ARC scoring
 - Annual repeat of skin prick test or specific IgE testing
2. *Reassurance around delayed anaphylaxis reactions when patients are at home and in comparison to subcutaneous immunotherapy*

The consensus from the literature seems to be that the risks of anaphylaxis are low and sublingual therapy has a lower risk than subcutaneous immunotherapy.

The APC therefore discussed and approved Grazax® 75,000 SQ-T oral lyophilisate (Standardised allergen extract of grass pollen) as an AMBER SI drug. Approved for use as disease-modifying treatment of grass pollen induced rhinitis and conjunctivitis in adults and children (5 years or older), with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen after failed maximum rescue therapy i.e. antihistamines, eye drops and nasal sprays. To be initiated by specialist with the first dose to be given in hospital, and then referred to the GP for continued prescribing for up to 3 years. The ARC score is used to assess progress of treatment on start of treatment and every 4 months by specialist to decide the efficacy of treatment.

ACTION:

- **JC/ABS to update the formulary websites once approved by VoY CCG.**

12. Compassionate Use/Free of Charge Scheme Requests

Nil this month.

13. NTAG Update

Nil this month.

14. Leeds/West Yorkshire APC Update

Nil this month.

15. RMOU Update

Nil this month.

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

16. Shared Care Guidelines for Approval

Nil this month.

17. HRT Guidelines

A final version of local HRT guidelines with the changes requested at the September 2021 APC meeting all made was presented to the APC.

It was noted that comments are still awaited from YFT consultants and that a formulary application for testosterone for use menopause is currently being prepared.

The APC agreed to delay approving the local HRT Guidance until the formulary application for testosterone for use menopause has been considered by the APC.

18. ACC Statin Intolerance Pathway

Discussed under item 10 – Bempedoic acid.

19. Amended Biologics Psoriasis Flowchart

An amended local Biologics Psoriasis Flowchart incorporating NICE TA723 Bimekizumab for treating moderate to severe plaque psoriasis was discussed and approved by the APC.

ACTION:

- **JC/ABS to update the formulary websites with link to updated Biologics Psoriasis Flowchart once approved by VoY CCG.**

Part 6 – Other Items of Business

20. Sativex® Letter – Prescribing of Sativex® spray in line with NICE NG144

The APC noted the letter dated 6th September 2021 sent to Trusts and CCGs by the England Chief Pharmaceutical Office re the Prescribing of THC:CBD spray (Sativex®) in line with NICE NG144.

The Y&S formulary currently reflects NG144 and shared care is in place. It is approved for moderate to severe spasticity in adults with multiple sclerosis, if other pharmacological treatments for spasticity are not effective or not tolerated in line with NICE NG144.

Harrogate formulary = RED drug - Restricted to use by Dr Davey (Consultant Neurologist) ONLY - following NICE NG144

Currently confirming what the current situation is in STHFT around the prescribing of Sativex® in line with NICE NG144.

21. Position Statement on the Prescribing of Co-Proxamol

A CCG position statement including de-prescribing guidance on co-proxamol prescribing was presented to and approved by the APC. This has come from Medicines Management Team discussions following a request for help by a GP in de-prescribing co-proxamol in a patient. Co-proxamol is an unlicensed medicine obtained from specific suppliers and this incurs variable and significantly high costs.

ACTION:

- **JC/ABS to update the formulary websites with link to position statement once approved by VoY CCG.**

Part 7 – Standing Items (for information only)

22. TEWV Medicines Optimisation Annual Report 2020/21

Circulated for information.

23. TEWV D&T Minutes – since March 2021

Latest minutes not yet available.

24. York & Scarborough Trust Drug and Therapeutics Committee Minutes

Latest minutes not yet available.

25. Harrogate Trust Medicines and Therapeutics Group Minutes – August 2021

Circulated for information.

26. Hull and East Riding Prescribing Committee (HERPC) minutes – May 2021 and July 2021

Circulated for information.

27. County Durham & Tees Valley APC Minutes – July 2021

Circulated for information.

28. West Yorkshire & Harrogate ICS APC Minutes – since April 2021

Latest minutes not yet available.

29. RDTC Monthly Horizon scanning – September 2021

Circulated for information.

30. NY&Y APC Meeting Dates 2022

Circulated for information.

Any Other Business

NY&Y Using Emollients with Oxygen Therapy Guidance

This document is intended to give a brief summary of the risks associated with oxygen use in conjunction with topical preparations and support a consistent approach across the patch for prescribers and respiratory teams including having a paraffin free choice available across the NYCCG area and an oil free lubricant to use on the face if a moisturiser is needed due to oxygen use.

There are a combination of risks involved:

- a) the risk associated with creams and ointments soaking into material, increasing the risk of flammability of the material.
- b) The fire risk associated with the combination of oxygen under pressure and oils and grease.
- c) The fire risk that can be posed by an enriched oxygen environment

This document seeks to highlight the risk, provide readily accessible patient information and take a proportionate view on product choice.

The document was approved by the APC along with the associated formulary updates.

ACTION:

- **JC/ABS to update the formulary websites once approved by VoY CCG.**

YFT Treatment Advice Notes

The APC noted that YFT will no longer be issuing Treatment Advice Notes as they are often illegible. Instead YFT will issue an outpatient prescription if urgent, or if not urgent make a recommendation on prescribing to the GP in the clinic letter.

It was noted that Harrogate Trust have an electronic Treatment Advice Note to avoid delays in GPs receiving clinic letters.

Date and time of next meeting

Wednesday 3rd November 2021, 2pm – 4.30pm, Virtual Meeting via Microsoft Teams