NHS
North Yorkshire and York
Area Prescribing Committee

# North Yorkshire & York Area Prescribing Committee

## Wednesday 3rd August 2022
## 2pm – 4.30pm, virtual meeting via Microsoft Teams

### Present

| Name | Job Title | Organisation | Mar 2022 | Apr 2022 | May 2022 | Jul 2022 | Aug 2022 |
|---|---|---|---|---|---|---|---|
| Ken Latta | Head of Medicines Optimisation | North Yorkshire Place | Y | Y | Y | Y | Chris Ranson |
| Dr Tim Rider | GP Prescribing Lead | North Yorkshire CCG | Y | Apols | Y | Y | Y |
| TBC | GP | North Yorkshire CCG | X | X | X | X | X |
| Laura Angus | Head of Medicines Optimisation | City of York Place | Apols | Y | Y | Y | Apols |
| Dr Shaun O'Connell | GP Lead for Acute Service Transformation | City of York Place | Y | Y | Y | Y | Apols |
| Dr William Ovenden | GP | City of York Place | Y | Y | Apols | Y | Y |
| Kate Woodrow | Chief Pharmacist | Harrogate and District NHS Foundation Trust | Y | Y | Apols | Apols | Y |
| Dr Ben Walker | Consultant and D&T Chair | Harrogate and District NHS Foundation Trust | Apols | Apols | Y | Y | Y |
| Dr S Brotheridge | Consultant | Harrogate and District NHS Foundation Trust | X | X | X | X | X |
| Stuart Parkes | Chief Pharmacist | York & Scarborough Teaching Hospitals NHS Foundation Trust | Y | Y | Y | X | David Preece |
| Dr Peter Hall | Consultant | York & Scarborough Teaching Hospitals NHS Foundation Trust | Y | Resigned | X | X | X |
| Dr Chris Hayes | Consultant and D&T Chair | York & Scarborough Teaching Hospitals NHS Foundation Trust | X | Y | X | Apols | Y |
| Tracy Percival | Formulary Pharmacist | South Tees Hospitals NHS Foundation Trust | Y | Laura Tweddle | Y | Apols | Y |
| | Consultant | South Tees Hospitals NHS Foundation Trust | X | X | X | X | X |
| Richard Morris | Deputy Chief Pharmacist | Tees, Esk and Wear Valleys NHS Foundation Trust | Chris Williams | Y | Y | Y | Apols |
| Shona McIlrae | Consultant Psychiatrist | Tees, Esk and Wear Valleys NHS Foundation Trust | X | X | X | X | X |
| Angela Hall | Public Health representative | North Yorkshire County Council | Apols | Apols | X | X | Y (Till 3pm) |
| Anita Dobson | Public Health representative | City of York Council | Y | Y (From 3pm) | Y (Till 3.30pm) | Apols | Y |
| Alison Levin | Finance representative | North Yorkshire Place | Kathryn Shaw-Wright | Apols | Kathryn Shaw-Wright | Apols | Kathryn Shaw-Wright |
| Steve Jordan (till Jan 2022) | Contracting representative | North Yorkshire Place | X | X | X | X | X |
| Hazel Mitford | Lay/patient representative | | Y | Y | Y | 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 | Susan Broughton |
| Faisal Majothi | Medicines Optimisation Pharmacist | City of York Place | Y | Y | Y | Y | Y |
| Jane Crewe | Formulary Pharmacist | York & Scarborough Teaching Hospitals NHS | Y | Y | Y | Y | Apols |

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|---|---|---|---|---|---|---|---|
| | | Foundation Trust | | | | | |
| Sara Abbas-Llewelyn / Emily Parkes | Formulary Pharmacist | Harrogate and District NHS Foundation Trust | X | X | X | X | X |
| Ian Dean | LPC Representative | | Y | Y | Y | Y | Y |
| Dr Sally Tyrer | LMC Representative | | X | X | Apols | X | X |
| Sara Moore | Deputy Chief Pharmacist | Harrogate and District NHS Foundation Trust | Y | X | Y | Y Kate Woodrow from 4.55pm | Apols |
| Chris Williams | Chief Pharmacist | Tees, Esk and Wear Valleys NHS Foundation Trust | Y | X | X | X | Y |

**In attendance**
Barry Ingram – RDTC – sharing papers on screen via MS Teams

The meeting was quorate with 13 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.

**Part 1**

**1. Apologies for absence and Quoracy Check**
Laura Angus, Shaun O'Connell, Stuart Parkes, Jane Crewe, Ken Latta, Sara Moore, Richard Morris

**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*

**3. Minutes of Previous APC & Decision Summary of Meeting Held 6th July 2022 (+outcome of HNY YMOC)**
The minutes of the July 2022 APC were approved as true and accurate record.

It was confirmed that the HNY IMOC has approved the recommendations from the July 2022 APC Meeting.

**4. Matters Arising Not on The Agenda & Declarations of AOB**
Nil

**5. Action Log**
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

LA/SP to discuss high-cost drugs and their approval under current block arrangements outside of the APC – *no update available.*

NY&Y New Product Application Form – updated
Updated NY&Y New Product Application Form circulated for comment to APC members. Final version will be presented at September 2022 APC.

Drugs for POTS (ivabradine, fludrocortisone, desmopressin, midodrine, pyridostigmine)
SOC has asked Cardiac Network for their views.
SP has confirmed current commissioning arrangements for POTS clinic at York & Scarborough Trust.
The issue will be discussed again at the September 2022 APC.

NHS National Patient Safety Alerts - Inadvertent oral administration of potassium permanganate
LA to take issue to ICB Medicines Quality and Safety Group and bring any actions for APC back to a future APC meeting – no update available.

DOAC decision making tool
Changes have been made as requested at last APC meeting and final version approved via email. ITEM NOW CLOSED

Type 2 diabetes guidance incorporating earlier place in therapy of SGLT2 inhibitors
On today's agenda.

Formulary Updates – NICE TA + MHRA DSU April/May 2022. Efudix, Imiqumoid, Otigo, Lenzetto, Phosphate Binders, Lixisenatide
JC/SAL to update the formulary websites.

Eye Chapter Formulary Alignment
JC/SAL to update the formulary websites

**Outstanding Actions from Previous APC Meetings**
Formulary status of alcohol dependence drugs for VoY CCG - Acamprosate and Disulfiram
Work still in progress. Noted NYCC revisiting their protocol for engaging with the APC when they are reviewing their public health medicines formularies in North Yorkshire, or when they are considering an addition

TEWV Anxiety Guidelines – updated
JEC/SAL to update the formulary websites once approved by VoY CCG – still to be actioned as not updated on TEWV website.
CR to add link to TEWV Anxiety Guidelines on APC website – still to be actioned as not updated on TEWV website.

County Durham & Tees Valley APC Cinacalcet SCG
RDTC still to discuss with /KL differences in monitoring in Cinacalcet SCG between CD&T and NY&Y outside of the meeting.

**Historic Actions Carried Over from June 2021 MCC meeting**
Hydroxychloroquine and Chloroquine Retinopathy: Recommendations on Monitoring 16 December 2020 - Updated RCOphth guidelines
Awaiting RMOC final guidance and national SCG template was published in July 2022. Needs discussion how national SCG might be adopted locally.

Melatonin YSTHFT Shared care
Still to progress paper due to current work pressures.

**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 – June 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:

- TA794 Diroximel fumarate for treating relapsing–remitting multiple sclerosis
- TA796 Venetoclax for treating chronic lymphocytic leukaemia
- TA798 Durvalumab for maintenance treatment of unresectable non-small-cell lung cancer after platinum-based chemoradiation
- TA801 Pembrolizumab plus chemotherapy for untreated, triple-negative, locally recurrent unresectable or metastatic breast cancer
- TA802 Cemiplimab for treating advanced cutaneous squamous cell carcinoma
- TA804 Teduglutide for treating short bowel syndrome

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:

- TA793 Anifrolumab for treating active autoantibody-positive systemic lupus erythematosus (terminated appraisal)
- TA795 Ibrutinib for treating Waldenstrom's macroglobulinaemia
- TA797 Enfortumab vedotin for previously treated locally advanced or metastatic urothelial cancer (terminated appraisal)

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:

- TA791 Romosozumab for treating severe osteoporosis
- TA792 Filgotinib for treating moderately to severely active ulcerative colitis
- TA799 Faricimab for treating diabetic macular oedema
- TA800 Faricimab for treating wet age-related macular degeneration

**Medicines Safety (MHRA drug safety update – June 2022)**
The group noted the drug safety updates for June 2022. The links are to be added to the relevant sections of the formulary.

**ACTION:**

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

The APC discussed NG219 Gout: diagnosis & management. It was noted all relevant drugs are currently on the formulary. But there needs to be some work done on the impact on primary care. The cost impact is also above the delegated authority of the APC so this guidance will need to be referred to the HNY IMOC.

**10. Other Formulary Issues**

Fidaxomicin granules

A new liquid formulation of fidaxomicin has recently been launched: Dificlir 40mg/ml granules for oral suspension. It is licensed for oral administration and also for administration via feeding tubes.

At present, only the 200mg tablets are listed in each formulary as Amber SI/Green Plus. approved.

It was agreed to add the new liquid formulation (Dificlir 40mg/ml granules for oral suspension) to the existing entries for fidaxomicin tablets in formularies in NY&Y as an AMBER SI drug.

This would provide a cost neutral option for patients who cannot swallow the tablets and for those who require their medication to be administered via a feeding tube.

**ACTION:**

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

Sacubitril/Valsartan RAG review

Sacubitril/valsartan (licensed for heart failure) is currently Amber- Specialist Initiation in line with NICE TA 388.

The Community Heart Failure Teams in York and Humber (cover Scarborough area) have requested a review of the status because only half of the nursing team are non-medical prescribers. This is not an issue for the Harrogate team who are all prescribers.

This difference is causing inequalities in care as half of the nursing team cannot initiate sacubitril/ valsartan and even if they can it may cause significant delays to care e.g. requesting prescription from a cardiologist.

The proposal is that it is move to Amber Specialist Recommendation in order that GPs may continue prescribing after a full review by the heart failure specialist nurse.

This was approved by the APC.

It was also agreed that the to mitigate the issue long term that all specialist nurses should also be trained as non-medical prescribers.

**ACTION:**

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

**11. New Drug Applications**

Oral Minoxidil for Female pattern hair loss

The APC discussed the formulary application from HDFT.

Oral Minoxidil requested as an option for Female Pattern Hair loss. 0.625mg alternate days OD then increase to daily as a second line option after topical minoxidil and spironolactone. Aware first line options are not listed as an option on the formulary however this is historically what has happened and is happening in practice.

Noted that topical forms of minoxidil for this indication are currently listed as BLACK drugs in the formulary.

APC asked to consider adding this as an option for hospital dermatologists to prescribe with a view for amber shared care in the future.

After discussion, the application was refused on grounds of equality as application does include use in males so APC could be open to an equality of access challenge. Also noted that topical forms are not approved on basis not an effective use of NHS resources but unlike oral minoxidil they are available to purchase over the counter. APC would accept a resubmission for use in both females and males.

Cyclogest® progesterone pessaries for miscarriage

The APC discussed the formulary application. Requested as an AMBER SR drug for:

- Patients with a confirmed intrauterine pregnancy presenting with bleeding in the first trimester of pregnancy with any history of previous miscarriage (not just recurrent miscarriage) – Off-label use

YSFT also wish to use for:

- Patients with high risk of preterm labour
  - previous late miscarriage preterm labour (16-34 weeks) or
  - short cervix on US scan (cervical length of 25 mm or less) performed (16-26 weeks)

This is as per NICE guidelines and also it is a recommendation from Saving Babies Lives.

Note - this product is already on York Formulary but with no indication or RAG status specified

Updated NICE guidance recommends the use of vaginal progesterone in those patients with a known IUP experiencing first trimester vaginal bleeding who have a history of miscarriage. Utrogestan® is not as widely available and there is more limited evidence with regards its use in pregnancy. Therefore, the majority of units plan to offer Cyclogest® (as we know it is a safe, readily-available and easy-to-administer preparation of progesterone).
Cyclogest® pessaries are used in almost all other EPUs and Fertility Centres in the UK. The evidence of benefit in all but a small number of patients is limited, but our patient group is better-informed than most and are seeking treatment according to the latest NICE guidance.

After discussion, the APC approved as a RED drug for use as per NICE guidance for:

- Patients with a confirmed intrauterine pregnancy presenting with bleeding in the first trimester of pregnancy with any history of previous miscarriage (not just recurrent miscarriage)
- Patients with high risk of preterm labour
  - previous late miscarriage preterm labour (16-34 weeks) or
  - short cervix on US scan (cervical length of 25 mm or less) performed (16-26 weeks)

This because all agreed that these patients should be under specialist care and review, and that GPs should not be asked to prescribe for these indications. Felt that GPs would be unlikely to take on responsibility for prescribing for these indications.

**ACTION:**

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

<u>Lyumjev® insulin</u>
At previous AOC meeting in May 2022 several questions were raised by the committee. The teams at York and Harrogate were contacted, but we have had no response from Harrogate Responses are from the York team. After discussion with Tara Kadis (Lead DSN Y&S) the anecdotal evidence and opinions from other trusts who are already using Lyumjev® seem to be that it is leading to better control in patients compared with Fiasp® so the team are obviously very keen that it is added.

The team would be happy to have for a 6-month period and audit the patients using it– 20 patients would be a realistic number.

Harrogate already have on formulary so if not approved there will be ongoing prescribing of Lyumjev® in primary care for patients already started on Lyumjev®.

After discussion, the APC approved for the treatment of diabetes mellitus in adults only as per licensed indication. To be second line after rapid acting analogue insulins and to be considered if post prandial hyperglycaemia (>9mmol/L 2 hours post meal) or patient unable to adhere to current insulin regimen by pre bolusing prior to meals (for example due to work related constraints)
Fiasp® is to remain on formulary because there may be patients who are unresponsive to Lyumjev® or allergic to Lyumjev®.

**ACTION:**

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

There was a general discussion of the need for work to be done locally on introducing biosimilar

insulins in NY&Y due to the cost-efficiencies to be made.

Ryego® for uterine fibroids
Given this is likely to be approved by NICE with a positive FAD the Gynaecologists would like to start preparing for what might be needed by the committee. Note FAD subject to appeal to be heard September 2022.
Need to consider RAG status and if guidelines needed. Should/ can the York RSS guidance be updated to achieve this and would this be acceptable to NYCCG (as was) and Harrogate Trust?
The APC agreed that want to a treatment pathway as part of APC adoption of the NICE TA when it is finally published. It was also noted that the RSS guidance may not be updated as RSS being replaced by an ICS clinical pathway system.

Glucagon prefilled pen (Ogluo®)
The APC discussed the formulary application.
Requested for treatment of severe hypoglycaemia in children aged 2 years and over with diabetes mellitus. To be used in children's services only.
May offer advantages over current product in that it is a pre-filled pen so does not require reconstitution before administration during hypoglycaemic event. It also does not require fridge storage.
Request for use in all newly diagnosed and existing children when current device expires or is used, but preferably swap all children over to the new product (supported by YSFT and HDFT).

The APC refused the application on the basis of significant cost difference over current Glucagen® product and no evidence presented of critical incidents due time to reconstitute current product.

**ACTION:**

- **TR to look if been any critical incidents with current product.**

Hydrocortisone MR (Efomdy®)
The APC discussed the formulary application from HDFT. Requested for treatment of Congenital Adrenal Hyperplasia (CAH) in adolescents aged 12 years and over and adults.
Approved by MHRA for treatment of CAH, this delayed release formulation enables diurnal rhythm matching of cortisol release to avoid early morning rises of active hormones as well as preventing the nighttime insomnia and sleep difficulties encountered in current steroid practice. This may therefore offer some advantages over existing formularies choices.

The APC discussed that this drug is not approved by the SMC. It also discussed what the evidence base is for matching diurnal rhythm and the clinical importance of this.

Decision deferred to fully appraise evidence around diurnal variation and steroid sparing effect.

**ACTION:**

- **BW to fully appraise plus summarise evidence with endocrinologists around diurnal variation and steroid sparing effect to come back to next APC meeting.**

**12. Romosozumab for severe osteoporosis**

NICE TA791: Romosozumab for treating severe osteoporosis was discussed at the July 2022 APC meeting and feedback was requested regarding the clinical pathway plus cost impact.

A rheumatologist at Harrogate is involved in regional work looking at a pathway for osteoporosis. In the meantime, it is proposed that the SIGN guidance is used which has a good flowchart

Speaking to the rheumatology/endocrine teams at the Trusts. Predicted numbers are as follows.

- HDFT 4-5 patients per year
- YSTH 6-8 patients per year

It was agreed to add romosozumab to the formulary as a RED drug in line with the NICE TA. Also agreed to use the SIGN guidance as an initial pathway and review when a regional pathway is produced

**ACTION:**

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

**13. Compassionate Use/Free of Charge Scheme Requests**

Nil this month.

**14. RMOC Update**

Nil this month.

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

**15. Shared Care Guidelines for Approval**

Nil this month.

**16. Publication of 18 National Shared Care Protocols**

The APC noted the publication of NHSE 18 National Shared Care Protocols on the 8th July 2022. The APC discussed how these could be adopted within North Yorkshire & York.

A list of current shared care protocols in North Yorkshire & York and their review dates was presented to the APC. It was agreed that where existing, robust, shared care guidance exists the APC would not prioritise adopting the new, national guidance and would update either when we had the capacity or when the existing SCG was due to be reviewed.

The priority for the APCs should be to seek to adopt the new, national guidance in areas where either our existing guidance is insufficient or completely new. Sodium valproate and hydroxychloroquine would both be examples of national SCG that would seek to adopt sooner.

It was noted that the HNY IMOC will also be discussing how these could be adopted for consistency across Humber and North Yorkshire.

The clinical content has been approved nationally with representation from all regions with input during the development, and via the consultation process undertaken by RMOC. So, when discussing locally need to understand what barriers, if any, may prevent localities from being able to adopt these national shared care protocol, and not the clinical content. These could include, but may not be limited to:

- Specialist service design and capacity
- Resource implications in both primary care and specialist clinics
- Compatibility with current digital communication methods
- Appropriateness of the listed indications for use of the medicine

Local clinicians would have to present exceptionally good reasons for no adopting a particular national shared care protocol.

**17. Type 2 diabetes guidance incorporating earlier place in therapy of SGLT2 inhibitors**

The updated local diabetes algorithm was presented at the last APC meeting (July 2022) and provisionally approved subject to a full consultation with HDFT.

Positive comments and recommendations were received, and the minor amendments have been incorporated within the guidance document.

The original scope of the review was to consider the new NICE guidance and update the local guidance accordingly. The current guidance is in line with NICE NG28 however HDFT

specialists are also proposing the use of GLP1 agonists at 'step 2', which is closely aligned with the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) recommendations.
It should be noted that NICE have only undergone a partial update of NG28 but the plan is to consider the rest of the treatment pathway relating to glycaemic control. At present GLP1 agonists are considered if triple therapy with metformin and two other oral drugs is not effective, not tolerated, or contraindicated. So, moving GLP1 agonists to step 2 is a significant change to the pathway which will have further significant financial impact over what has already been estimated previously.

The APC that guidance should be in line with NICE or not further amend to include GLP1 agonists at 'step 2' of the algorithm. (Hybrid guidance - partially adopting NICE and EASD-ADA). This is because a full review of NICE guidance including GLP-1 is in the NICE workplan.

It was agreed to bring back to the next APC to finally approve as confirmation required that the Hb1Ac thresholds for treatment escalation are correct and match NICE.

**ACTION:**

- **FM to confirm Hb1Ac thresholds for treatment escalation are correct and match NICE, and then bring back guideline to next APC for final approval.**

General discussion took place on the need to ensure full consultation on agenda items was discussed. There needs to be early engagement/consultation with relevant clinicians, with department buy-in/view and not just that of an individual. Cover sheets for agenda items also need to be completed in full.

**18. Biologics pathway for IBD updated to reflect new NICE guidance TA792**

The APC approved the updated pathway to include Filgotinib for treating moderately to severely active ulcerative colitis as per the recently published NICE TA.
It was noted that this is in a format that is currently working well, and so no other changes are required.

General discussion took place on the need to have system in place for document control of APC guidelines.

**ACTION:**

- **RDTC to discuss with CR/JC putting in place in system for document control of APC guidelines.**

**Part 6 – Other Items of Business**

**19.** Nil this month.

**Part 7 – Standing Items (for information only)**

**20. TEWV D&T Minutes – May 2022**

Not yet available.

**21. York & Scarborough Trust Drug and Therapeutics Committee Minutes – July 2022**

Circulated for information.

**22. Harrogate Trust Medicines and Therapeutics Group Minutes – since May 2022**

Not yet available.

**23. County Durham & Tees Valley APC Minutes – May 2022**

Not yet available.

**24. West Yorkshire & Harrogate ICS APC Minutes – since February 2022**
Circulated for information.

**25. Humber APC Minutes**
Not yet available.

**26. RDTC Monthly Horizon scanning – July 2022**
Circulated for information.

**Any Other Business**
Harrogate MTG
Noted this now meets on alternate months with meeting dates aligned with those of YSFT D&T. It's terms of reference have also been updated to reflect changes to its remit now the APC has been established.

**Date and time of next meeting**
Wednesday 7th September 2022, 2pm – 4.30pm, Virtual Meeting via Microsoft Teams