Northern Treatment Advisory Group

Minutes of meeting held on the 17th of January 2023, 9-11am

Virtual Online Meeting via Microsoft Teams

Present:

- Claire Bradford – ICB Medical Director & Chair of NTAG.
- Gavin Mankin - Principal Pharmacist Medicines Management, RDTC (professional secretary)
- Robert Lapham - Formulary Pharmacist, South Tyneside & Sunderland NHS Foundation Trust.
- Matthew Lowery - Formulary Pharmacist, Newcastle upon Tyne NHS Foundation Trust.
- Helena Gregory – Medicines Optimisation Pharmacist and Clinical Quality Team Lead North Cumbria (from 09.48am).
- Toks Sangowawa – Clinical Advisor/Locum Consultant in Public Health, South Tyneside MBC.
- Jo Linton – Public Heath Pharmacy Advisor, Stockton & Hartlepool.
- Helen Seymour – NENC AHSN Medicines Optimisation Workstream Lead.
- Rachel McMahon – GP, NENC Regional LMC representative.
- Susan Turner – Professional Secretary, North of Tyne, Gateshead & North Cumbria APC.
- Charles Welbourn – ICB Director of Finance (North Cumbria).
- Robin Mitchell – Medical Director, NENC Clinical Network.
- Tracy Percival – Pharmacist, South Tees Hospitals NHS Foundation Trust.
- Andy Lloyd – Consultant Anaesthetist and Chair of D&T, South Tees Hospitals NHS Foundation Trust.
- Hayder Qureshi – Professional Secretary, South Tyneside & Sunderland APC.

In Attendance:

- Dan Newsome – Principal Pharmacist – Medicines Management, RDTC
- Miranda Trevor – Public Health Registrar
- Tanja Braun – Consultant in Public Health, Stockton-on-Tees.

The meeting was quorate.

Members were welcomed to the meeting, and a round of introductions were made.

1) Apologies for absence

Apologies were received from: David Campbell, Jim Welch, Matthew Grove, Simon Hill

2) Declarations of interest

No declarations were received prior to the meeting on receipt of the agenda and when the Chair invited any declarations of interest to be made none were declared.

3) Draft minutes November 2022 meeting

The group approved the minutes of the 15th November 2022 NTAG meeting with minor amendments to grammar/spelling.

Noted that awaiting confirmation for ICB Governance Team as to what can be published on NTAG website including if meeting minutes can be published.

ACTION: Secretary to submit November 2022 minutes to NENC Medicines Committee.

4) Matters arising

- Review of NTAG recommendations relating to the eye – still awaiting feedback from NE Retina Group as to which recommendations require review. Have approached NuTH for their input as no formal ophthalmology clinical network exists, and response awaited.

5) Action log

NTAG interim Terms of Reference – amendments November 2022
Sent to NENC Medicines Committee.
NTAG will be a subgroup of NENC Medicines Committee. The NENC Medicines Committee will be a subcommittee of the ICB Executive subject to ICB Board approval in March 2023.
Note that at this stage neither the ICB Medicines Committee or NTAG has any delegated authority for decision making and everything needs to be escalated to the ICB Executive for approval.

Review of NTAG recommendation on sodium oxybate (Xyrem®) in the management of narcolepsy with cataplexy in adult patients in light of RMOC position statement
Recommendation drafted and submitted to December 2022 NENC Medicines Committee. Now sent to Januart 2023 ICB Executive for financial sign off. Awaiting publication on ICB website of the decision summary with regards to medicines from January 2023 ICB Executive.

Dexcom ONE formulary application
Secretary still to raise clinical waste disposal/collection from patients in the community issue with ICB Director of Medicines and Pharmacy.
Recommendation drafted and submitted to December 2022 NENC Medicines Committee. Now sent to January 2023 ICB Executive for financial sign off. Awaiting publication on ICB website of the decision summary with regards to medicines from January 2023 ICB Executive.

Review of NTAG recommendation for vaginal devices for stress urinary incontinence
Recommendation drafted and submitted to December 2022 NENC Medicines Committee. Now sent to January 2023 ICB Executive for financial sign off. Awaiting publication on ICB website of the decision summary with regards to medicines from January 2023 ICB Executive.

Review of NTAG recommendation for transanal irrigation
Recommendation drafted and submitted to Dec 2022 NENC Medicines Committee. Now sent to Jan 2023 ICB Exec for financial sign off. Awaiting publication on ICB website of the decision summary with regards to medicines from January 2023 ICB Executive.

New NOGG Guideline for the management of osteoporosis
Second draft of regional guideline in progress and will come back to a future NTAG meeting for approval.

Hosting/approval of guidelines

Susan Turner and RDTC now acting as a link between the "Mark Dornan" Teamnet/Health Pathways guidelines group and NTAG/ICS medicines committees. Awaiting confirmation of the process for this.

Noted access to GP Teamnet is at practice level and not all clinicians are able to access the resources it hosts. This is outside the remit of NTAG.

6) Appeals against previous NTAG decisions

Nil received since last meeting.

7) NTAG interim Terms of Reference

NTAG interim Terms of Reference updated at November 2022 NTAG meeting and presented at NENC ICB Executive in December 2022. They still require sign off from ICB Board as only the Board can approve the creation of and the delegation to subgroups.

NTAG makes a recommendation to the NENC Medicines Committee who then approve it for submission to ICB Executive for financial sign off. Currently no committees in ICB can have delegated authority from ICB Board.

Agreed that NTAG will take on all existing formulary functions from current Area Prescribing Committees (APCs) from January 2023.

NENC Medicines Committee agreed the revised interim process for formulary applications where they continue to be appraised by trust formulary pharmacists and then are forwarded on to NTAG for decision. Applications already in the APC process should continue via that route until complete, with any future applications going direct to NTAG.

The timeframe for a single formulary is April 2023. It is noted that at that time a number of drugs may still be considered "under review but hope that this number will be significantly lower following further discussion in January/February.

The following new amendments were presented to and approved by NTAG:

- Section 2 – add approval of NHSE commissioned NICE TA drugs in addition to ICB commissioned ones once across the NENC (note that NTAG to take on all formulary functions from APC)
- Section 2 – add responsibility for considering all formulary applications and amendments including any formulary amendments relating to MHRA Drug Safety Updates.
- Section 8 – quorum – may need updating based on advice still to be received from ICB.
- Membership
    - need to identify new additional GP representation to fill gaps in NTAG membership. Noted than new Clinical Leads across ICB coming into post and Chair of NTAG is working to identify who will have remit for medicines therefore may be a candidate to join NTAG.
    - Dr Simon Hill to join as new consultant representative from NuTH.
    - Dr Yincent Tse – proposed as addition as paediatric representative from NuTH to be co-opted when issues relating to paediatrics arise, and as deputy for Simon Hill.

NTAG members proposed the following further amendments which were supported by NTAG:

- Page 4 – remove “Treatments which are not appraised by NTAG may instead need to be considered locally by, for example, an area prescribing committee or similar. These would be expected to be low-impact agents” as formulary management role moving from APCs to NTAG.
- Page 11 – typo to correct “Reliable evidence will usually be required from good quality, rigorously appraised studies and where possible only published information will be used, however on occasion it may be necessary to consider evidence from other sources.”
- Page 1 – add consider implications on pathways, finances, and commissioning of services to “To make a recommendation on the approval of ICB commissioned NICE TA drugs once across the NENC to the NENC ICB.”

ACTION: Secretary to send to NENC Medicines Committee for approval.

8) Glucagon (Ogluo®) for hypoglycaemia

NTAG discussed the potential approval of the Glucagon (Ogluo®) prefilled syringe in the NENC.

Ogluo® is indicated for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus. Ogluo® is available in a 0.5mg and 1mg strength. It is a single-use pre-filled pen

The current product is GlucaGen HypoKit 1 mg powder and solvent for solution for injection given by subcutaneous or intramuscular injection. It does not come in a 0.5mg strength for children.

Unlike the current glucagon kit (powder in a vial plus pre-filled syringe with water for injection) which requires several stages of preparation, Ogluo® has been designed to be used in a simple two-step process: pull the red cap off and push the yellow end down on the skin and hold for 5 seconds until the window turns red. It may be appropriate in some individuals but would likely not be appropriate for routine selection over other similar products such as GlucaGen Hypokit, due to the increased cost. As this preparation is a ready-to-use pre-filled product time saved in administration may be beneficial for some patients, off-setting (in a clinical sense) any delay in pharmacodynamic action.

NTAG discussed the possible advantages and disadvantages of the Olugo®.

The EMA in their assessment report discuss one study of 132 adults with type 1 diabetes who were given both Ogluo and GlucaGen (the reference medicine) in a cross-over design. They note that GlucaGen appears to raise blood glucose to an “acceptable” level (range not stated) after 10.4 minutes, and that Ogluo does so after 14.8 minutes. They highlight this difference, noting that “although improvement in blood glucose levels with Ogluo may be delayed by about 4 minutes, preparation of Ogluo injections is quicker compared to injections that need to be made up by dissolving the glucagon powder first”.

Questions raised by NTAG members included:

- Any evidence of risk/harms/clinical incidents associated with current product? Noted that no real-life studies currently available. Gathering this evidence via current incident reporting may

be difficult because incidents could occur outside of a health care setting so would such incidents be reported, and how incidents may recorded/coded.

- How many GlucaGen Hypokit are actually used vs how many expire before used?

In summary, there is a conceivable benefit for Ogluo® in a subset of patients who are unable to compound the GlucaGen Hypokit product in a timely manner if suffering from severe hypoglycaemia, or where family/carers are unable to compound GlucaGen Hypokit. But does this advantage justify the cost.

The North East and North Cumbria Diabetes Network have been approached to provide a clinical perspective on this group/groups of patients who are likely to gain most benefit. Unfortunately, there is yet to be any feedback from them.

GlucaGen Hypokit costs £11.52 per 1 vial (1mg). Ogluo® costs £73.00 per pre-filled syringe. Whilst Ogluo is more than 6-fold the cost of GlucaGen Hypokit, there may be a subset of patients for whom it is more appropriate to provide a pre-filled syringe rather than powder and solvent for solution. Routine prescribing of Ogluo where the needs of the patient can be met with GlucaGen Hypokit would not be an appropriate use of NHS resources due to the cost difference.

If all patients using Glucagon were to be switched to Ogluo® this would represent an increased cost of £453k per year for NENC ICB.

NTAG agreed that it was unable to make a recommendation on Olugo® until the views of clinicians particularly on potential place in therapy had been gathered from the NENC Diabetes Network.

ACTION: RDTC with support of Robin Mitchell to contact NENC Diabetes Network for their views on Olugo® and potential place in therapy.

9) Gabapentinoids for intractable itch with severe burns

The formulary request received for gabapentinoids for intractable itch with severe burns was presented to NTAG. This was initially submitted to the North of Tyne APC but due to this being a regional service and the benefits of having a single North East and North Cumbria ICS position on this, it was agreed that would be considered once by NTAG. The APC also recognised the concerns around gabapentinoid use in general.

The request is from the Regional Burns Unit at the RVI where pregabalin and gabapentin are already used for this indication as a hospital only drug. This application is formalising this practice and requesting transfer of prescribing into primary care

The evidence is as per the application submitted. Gabapentin and pregabalin are drugs licensed for epilepsy and neuropathic pain. This would be an unlicensed indication. Noted that no independent evaluation of the evidence presented in the application has been done.

Burn scars can be incredibly itchy, affecting a patient's quality of life and causing wounds from repeated scratching. Some of patients have extensive scars with severe itch symptoms. New research shows that antihistamines are only partly helpful to treat itch related to scars, and that gabapentin and pregabalin are better at treating itch in burn patients. This knowledge is widely

known about in the burn community but not amongst general practitioners, who may be reluctant to continue these prescriptions in the community for our patients.

Evidence is based on four randomised controlled trials which are as also included in the systemic review included by the RDTC with the meeting papers.

The addition of gabapentin and pregabalin to the formulary for itch indication will allow these important medications to be prescribed in hospital and continued in the community to help burn survivors with their symptoms while they recover and return to their pre-injury activity.

The costings prepared by the RDTC based on the current Drug Tariff price for pregabalin and gabapentin were presented to NTAG. Applicant suggests required for 100 patients a year (50 children, 50 adults)

Requested as a Green Plus (Specialist Initiation/Recommendation) drug. Discharge with one month supply, look to GP for ongoing prescriptions thereafter until weaned by burn service. Average 6-8 weeks treatment course.

The following points/questions were raised in the discussion:

- Safety profile of gabapentioids is established for other indications.
- Why pregabalin first algorithm for adults and not gabapentin as per the paediatric algorithm?
- If weaning at six to eight weeks does it need prescribing to come out into primary care? Concern that use may increase use for intractable itch in general.
- Unlicensed indication for which there is no supporting NICE guidance plus weaker evidence base compared to other indications. This a specialist indication for which primary care has little or no experience. Patient numbers per GP practice are also likely to be just one to two per practice so concerns around familiarity with prescribing for this indication in primary care.
- Primary acre is under pressure to reduce gabapentinoid use in general particularly for unlicensed indications with similar evidence base to this.
- What support is available from secondary care to support the weaning off treatment? This is not fully covered in the algorithm included in the application in particular for adults. There were concerns of the potential impact on primary care workload that weaning will have.
- May be more suitable for shared care especially for weaning.
- Discussed potential equity issues particularly around patients being able to access this treatment from regional centre if they live some distance away, which provides some of the rationale for transfer to primary care prescribing
- This situation would lend itself to a model where secondary care could prescribe via EPS, if this were available, to community pharmacy.

NTAG agreed it was unable to make a recommendation today as a number questions were raised which require a response from applicant. But it recognised that this is a request from a regional service for a niche indication, noting that it is an unlicensed indication.

ACTION: Matthew Lowery to go back to applicant with questions raised by NTAG.

10) Teriparatide use outside of NICE guidance as per NOGG

NTAG discussed the formulary application received for the use of teriparatide outside of its current NICE TA as an alternative to romosozumab in the management of osteoporosis.

Teriparatide is a 20microgram subcutaneous injection once daily via pen device for 24 months maximum (lifetime exposure: course not to be repeated).

The licensed indication for teriparatide is for osteoporosis in postmenopausal women and in men at increased risk of fractures.

NICE TA161 (October 2008, updated February 2018) approves teriparatide as second line use in secondary prevention only.

Indication for which product is requested in this application is (Biosimilar teriparatide only) for treatment of osteoporosis in postmenopausal women and in men who:

- Are at very high risk and imminent risk of fracture as per NOGG (2021) guidelines
- For first line use for secondary prevention in this specific group
- Where romosozumab (NICE TA791) is either not indicated (all men) or contraindicated (women with significant CV disease)

If approved would be a RED (hospital only) drug supplied via Homecare. Noted it is no longer a tariff excluded drug.

Simultaneous to the publication of NICE TA791 for romosozumab, The National Osteoporosis Guideline Group (NOGG) published its updated 2021 guideline, which provides a rationale for “severe osteoporosis” left open by NICE. Controversially (and the whole purpose for this submission), NOGG suggested using biosimilar teriparatide as an alternative first line anabolic agent to romosozumab, in patients where romosozumab was not indicated (essentially, men) or had contraindications to its use (women with cardiovascular disease: romosozumab carries a warning, teriparatide does not). NOGG did not conduct a formal cost-efficacy analysis but stated because biosimilar teriparatide was now available and cheaper this would be cost-effective.

Clinically, this is a rational suggestion because teriparatide (like romosozumab), is now known to produce larger changes in BMD and better reduction in fracture risk when used in patients naïve to antiresorptives/ bisphosphonates. Although it is inferior to romosozumab in terms of fracture risk reduction, it is clearly superior to oral bisphosphonates (particularly in the spine).

Teriparatide has a good safety profile. It does however require the patient to self-inject daily for two years; many patients may prefer weekly oral or annual bisphosphonate infusion therapy simply for convenience reasons.

Romosozumab requires two injections per month. It is unlikely that patients eligible for romosozumab would prefer teriparatide, although if they did this would be a far cheaper option

Proposed that biosimilar teriparatide will be offered as an option for first line treatment of patients who:

- Are at very high risk of fracture as determined by FRAX (Ten-year risk of major fracture >32% or hip fracture >9%) based on clinical factors and DXA bone scan results

- And are at imminent risk of fracture (have sustained a documented fragility fracture within the last two years)
- And have contraindications to romosozumab therapy (in most cases a documented history of cardiovascular disease) or romosozumab is not indicated (all men)

For women without contraindications, romosozumab will be offered by preference as per NICE TA791.

Patients will be offered a two-year course of biosimilar teriparatide, followed by anti-resorptive therapy (either oral or iv bisphosphonates, or denosumab).

Full ICS wide osteoporosis guideline currently in development but will cleave closely to NOGG (2021) guideline. This formulary approval is being sought to clarify teriparatides role in that guideline.

It was noted that no independent evaluation (e.g. by RDTC) of the evidence presented in the application has been done. Also, would need to get estimated total patient numbers across the NENC plus support from across the NENC to inform any NTAG recommendation.

NTAG agreed to defer a recommendation until information on impact across NENC available and views of clinicians across wider NENC known. NTAG also felt given Matthew Grove's apologies today unable to have an informed discussion around evidence and interpretation of NOGG.

ACTION: Secretary to ask Matthew Grove for patient numbers across ICB and views of clinicians across region.

ACTION: Matthew Lowery to confirm if in tariff or out of tariff drug.

11) NENC ICS recurrent UTI prophylaxis guideline

A recurrent UTI ICS guideline has been developed by the AMS workstream and approved by the ICS AMR board.

This guideline was presented at November 2022 meeting of NTAG and the following changes were requested before NTAG would consider approving:

- Nitrofurantoin monitoring requirements - renal and hepatic function monitoring is discussed but is not specific unlike the section on trimethoprim.
- Vaginal oestrogen advice needs extra detail - this is as per NICE NG112
- Rescue packs – needs extra detail on what is recent tests, and frequency of review – this would always be subjective regardless of the infection
- General comments around modifying some the language used – related mainly to emphasizing shared decision making with the patient. It would be helpful if the antimicrobial group could recommend a small selection of patient and clinician resources for us to use to implement this guideline in practice, as follow-on work.
- It is good practice to write a clear end date on the antibiotic prescription so that it is clear to patient, other colleagues, and community pharmacy when the prophylactic course should end / be reviewed.

These changes have been made by the authors and final version presented for approval.

ACTION: Secretary to send to February 2023.NENC Medicines Committee for approval.

ACTION: Secretary to feed back to authors suggested changes to flowchart to match main document.

12) Regional Medicines Optimisation Committee

Nil this month.

13) RDTC monthly formulary amendments – NICE TA/MHRA Drug Safety Updates – November and December 2022

The RDTC Monthly Formulary Amendments – NICE TA/MHRA Drug Safety Updates – November and December 2022 were presented to NTAG for NTAG to make a recommendation to the NENC Medicines Committee on the formulary status and approval of medicines with a NICE TA issued in November and December 2022

It was agreed at the October 2022 and December 2022 NENC Medicines Committee that NTAG should begin to manage NICE technology appraisals entry for the NENC system from its November 2022 meeting. This would mean that the local Area Prescribing Committees (APCs) would no longer need to undertake this function, however they would continue to assess their own formulary applications at this stage, with any decisions being communicated to NTAG.

There is no delegated financial authority yet for the NENC Medicines Committee or NTAG, so all recommendations need to be submitted to the ICB Executive for approval.

The formulary will reflect the NICE TA for NHSE commissioned drugs with a NICE TA.

All ICB commissioned NICE TAs published in November 2022 and December 2022 are not expected to have a significant cost impact and expected to fall below the £250,000 threshold of the ICB Director of Medicines and Pharmacy. None of these NICE TAs have been considered by the three existing APCs previously.

A proposed timetable for consideration of NICE TAs in the NENC in future and process for a NENC formulary/commissioning decision on ICB Commissioned drugs with a NICE TA was presented to and approved by NTAG in November 2022. This has now been submitted to the January 2023 ICB Executive for approval.

NTAG agreed with the suggested formulary status for each drug with a NICE TA published in November and December 2022.

ACTION: Secretary to send recommendations to February 2023 meeting of NENC Medicines Committee and then ICB Executive for final sign off.

14) APC Decision Summaries

- **CD&T APC November 2022**

- **ST&S APC December 2022**
- **NoTGNC January 2023**

The committee received in the recent decisions from the three area prescribing committees of the ICS; County Durham & Tees Valley APC; North of Tyne, Gateshead & North Cumbria APC; and South Tyneside & Sunderland APC. NTAG noted the decisions from the APCs, and they will now be submitted to the next NENC Medicines Committee/ICB Executive for approval. As neither the Medicines Committee nor NTAG has been delegated any authority from the ICB executive, all decisions will need to be submitted to the ICB Executive for decision.

As neither the medicines committee nor NTAG has been delegated any authority from the ICB executive, all decisions will need to be submitted to the ICB Executive for a decision.

No financial impact information has been provided by the APCs, therefore the Medicines Committee/NTAG needs to consider how this information will be coordinated centrally if it is to be provided to the ICB.

ACTION: Secretary to send recommendations to February 2023 meeting of NENC Medicines Committee and then ICB Executive for final sign off.

15) Workplan

The group discussed the work plan.

It agreed to add the following topics:

- Olguo® - for January 2023 meeting
- Gabapentinoids for intractable itch with severe burns – for January 2023 meeting
- Teriparatide use outside of NICE guidance as per NOGG
- Single ICS formulary
- NENC DMARD share care guidelines
- Regional menopause guideline
- Formulary applications:
  - Tacalcitol lotion for psoriasis vulgaris
  - Trifarotene cream for acne

Updates to locality dressing formularies/guidelines will come to NTAG once Trusts/subICBs have updated versions for approval. A single ICB dressing formulary is not a priority at this stage so it is important that existing dressings formularies/guidelines continue.

Post meeting: Linzagolix for uterine fibroids removed from NTAG workplan as now in NICE timetable.

An application NuTH for Nephrotrans® will be picked through ICB formulary development work as already on formulary in ST&S.

16) County Durham & Tees APC Minutes – November 2022

Circulated for information.

17) South Tyneside & Sunderland APC Minutes – December 2022
Circulated for information.

18) North of Tyne, Gateshead & North Cumbria APC Minutes – January 2023
Circulated for information.

AOB
Nil

No other business was raised, and the meeting concluded.

The date of the next meeting was agreed to be 21st March 2023 and will be held virtually via Microsoft Teams.

Minutes produced by G Mankin, Professional Secretary to NTAG, 17th January 2023