Northern Treatment Advisory Group

Minutes of meeting held on 21st March 2023, 9-10.30am

Virtual Online Meeting via Microsoft Teams

Present:

Position		Lead	Voting Member	Jan 2023	March 2023
Chair		Dr Claire Bradford *Medical Director, ICB*	Yes	✓	✓
Secretary		Gavin Mankin, Principal Pharmacist – Medicines Management, Regional Drug & Therapeutics Centre (Newcastle)	No	✓	✓
Provider hospital trusts clinical representative	**Mental Health Trust**	*Tim Donaldson Chief Pharmacist Northumberland Tyne & Wear NHS Trust*	Yes	*X*	✓
	South Tees Hospitals	*Dr Andrew Lloyd Consultant Anaesthetist and Chair of South Tees D&T*	Yes	*Tracy Percival*	✓
	Newcastle Hospitals	*Dr Simon Hill Consultant in Clinical Pharmacology & Therapeutics and Clinical Toxicologist*	Yes	*Apols*	✓
		Mr Matthew Lowery Formulary and Audit Pharmacist	Yes	✓	✓
	Northumbria Healthcare	*Dr Matthew Grove Consultant Rheumatologist, Northumbria Healthcare Foundation Trust*	Yes	*Apols*	✓
	South Tyneside & Sunderland Foundation Trust	*Mr Robert Lapham Formulary Pharmacist Sunderland Royal Hospital*	Yes	✓	✓
Primary Care	**General medical practitioners**	*Dr James Carlton GP, County Durham*	Yes	*X*	✓
		Dr Janet Walker General Medical Practitioner, Tees Valley	Yes	*X*	✓
	Medicines management	*Helena Gregory Medicines Optimisation Pharmacist and Clinical Quality Team Lead North Cumbria*		✓	*Apols*
	Finance	*Charles Welbourn Finance Director (North Cumbria)*		✓	*Apols*
Quality & Safety ICS representative		*Vacant*	Yes	*X*	*X*
Patient representative		*Jim Welch*	Yes	*Apols*	✓
Public Health		*Dr Toks Sangowawa Clinical Advisor/Locum Consultant in Public*	Yes	✓	✓

		Health, South Tyneside MBC *Clinical Advisor IFR North*			
Local Authority Pharmacist (1 representing all stakeholder local authorities)		*Jo Linton* *Public Health Pharmacy Adviser* *Stockton and Hartlepool*	Yes	✓	✓
AHSN		*Helen Seymour* *NENC AHSN Medicines Optimisation Workstream Lead*	Yes	✓	✓
NECN Clinical Network		*Robin Mitchell* *Clinical Director, NENC Clinical Networks*	Yes	✓	*Apols*
LPC (1 representing all stakeholder LPCs)		*Vacant*	Yes	*X*	*X*
LMC (1 representing all stakeholder LPCs)		*Rachel McMahon*	Yes	✓	*Apols*
Stakeholder APC (Chair+Sec)	**County Durham & Tees Valley APC**	*Rupert Smith* *GP Prescribing Lead, Tees Valley*	No	*X*	*X*
	North of Tyne, Gateshead and North Cumbria APC	*David Campbell* *Chief Pharmacist Northumbria Healthcare Foundation Trust*	No	*Susan Turner*	*Susan Turner*
	South Tyneside & Sunderland APC	*Colin Bradshaw* *GP Prescribing Lead South Tyneside*	No	*Hayder Quershi*	*X*

In attendance:

- Dan Newsome – Principal Pharmacist – Medicines Management, RDTC
- Conor McCahill – Pharmacist, RDTC

The meeting was quorate.

NTAG noted that Claire Bradford, the current NTAG chair, is retiring today so this will be her last meeting. NTAG wished to express their thanks and gratitude to Claire for all her support and hard work on behalf of NTAG since she took on the role of Chair. The new chair of NTAG will be Janet Walker.

Members were welcomed to the meeting.

1) Apologies for absence

Apologies were received from: Tanja Braun, Robin Mitchell, Helena Gregory, David Campbell, Charles Welbourn, Rachel McMahon.

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 January 2023 meeting

The group approved the minutes of the 17th January 2023 NTAG meeting subject to a reference in Item 15 re wound care formulary, changing to read “will be approved by NTAG” not APCs as currently reads.

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

ACTION: Secretary to submit January 2023 minutes to NENC Medicines Committee.

4) Matters arising

- Review of NTAG recommendations relating to the eye – despite several attempts to contact NE Retina Group, and ophthalmology at NuTH and STSFT as to which recommendations require review, no response received. Therefore agreed to remove as NTAG action as NTAG website states that "Where a decision is >24 months old; these are highlighted in red. If you are a clinician working within the NTAG region and would like to prioritise an old decision for re-review, please contact the professional secretary."

5) Action log

NTAG interim Terms of Reference – further amendments
Approved at February 2023 NENC Medicines Committee. ITEM NOW CLOSED.
Noted that the ICB are reviewing the membership of all the committees in the proposed NENC medicines governance structure. As part of this, a letter has gone out to all APCs in the NENC seeking nominations for each committee. Once nominations are received, the ICB medicines team will review to ensure a balanced membership in terms of geography, consultant/GP vs pharmacist, and balance of stakeholders across all committees. Current NTAG membership may change in light of nominations received.

Glucagon (Ogluo®) for hypoglycaemia
RDTC, with support of Robin Mitchell, to contact NENC Diabetes Network for their views on Ogluo® and potential place in therapy. Emailed 18.1.2023, awaiting response. Agreed to follow up again prior to May 2023 NTAG meeting and if no response remove as an NTAG action.

Gabapentinoids for intractable itch with severe burns
On today's agenda.

Teriparatide use outside of NICE guidance as per The National Osteoporosis Guideline Group (NOGG)
On today's agenda.

NENC ICS recurrent UTI prophylaxis guideline
Approved at March 2013 ICB Executive Committee. ITEM NOW CLOSED.

RDTC monthly formulary amendments – NICE TA/MHRA Drug Safety Updates
Recommendations from January 2023 NTAG approved at March 2023 ICB Executive Committee. ITEM NOW CLOSED.

APC decision summaries – CD&T APC November 2022, ST&S APC December 2022, and NoTGNC January 2023
Approved at March 2023 ICB Executive Committee. ITEM NOW CLOSED.

New NOGG guideline for the management of osteoporosis
Draft in progress.

Review of NTAG recommendation on sodium oxybate (Xyrem®) in the management of narcolepsy with cataplexy in adult patients in light of RMOC position statement
Secretary to request audit from NuTH and STHFT in 12 months' time and present this to NTAG. Final recommendation now published on ICB website following approval of January 2023 ICB Executive.

Dexcom ONE formulary application
Final recommendation now published on ICB website following approval of January 2023 ICB Executive. ITEM NOW CLOSED.
Waste issue has been picked up by ICB Director of Medicines and Pharmacy. ITEM CLOSED FROM NTAG perspective.

Review of NTAG recommendation for vaginal devices for stress urinary incontinence
Final recommendation now published on ICB website following approval of January 2023 ICB Executive. ITEM NOW CLOSED.

RDTC monthly formulary amendments – NICE TA/MHRA Drug Safety Updates – August, September, and October 2022
RDTC final recommendation now published on ICB website following approval of January 2023 ICB Executive. ITEM NOW CLOSED.

6) Appeals against previous NTAG decisions
Nil received since last meeting.

7) Gabapentinoids for intractable itch with severe burns
The formulary request received for gabapentinoids for intractable itch with severe burns was presented again to NTAG.

The responses from the applicant to the questions raised by NTAG at its January 2023 meeting were discussed. The applicant has confirmed that:

- Treatment is often up to 6 months, with patients with 50% burns requiring treatment for at least 6 months.
- All weaning would be undertaken by the specialist burns service.
- A shared care guideline could be developed (essentially weaning would be undertaken with all dose adjustments being directed by the specialist burns service).
- Gabapentin now first choice gabapentinoid in both children and adults, and treatment guideline updated to reflect this. Confirmed no direct studies in burns itch to show the superiority of pregabalin over gabapentin so would recommend using gabapentin first line.

NTAG discussed and agreed to recommend approval as a GREEN+ drug as points raised at January 2023 NTAG meeting now addressed by applicant, and all weaning will be done by the specialist burns service (note: gabapentinoids are currently classed as GREEN drugs for neuropathic pain).

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

8) 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. Note: it is no longer a tariff excluded drug.

Simultaneous to the publication of NICE TA791 for romosozumab, 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 that 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.

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.

NTAG noted that teriparatide, when used for this indication, appears to be cost-effective and meet the cost-effective threshold that NICE would use.

This application has support from the relevant clinicians from across the region.

NTAG noted that approval of teriparatide to the formulary for these extended indications would have resource and commissioning implications in terms of services being commissioned to see these patients and provide this drug. Issues with the current block contract arrangements were discussed.

NTAG agreed to recommend approval as a RED drug and to flag the cost/service implications to the Medicines Committee and ICB Executive for consideration.

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

9) RDTC monthly formulary amendments – NICE TA/MHRA Drug Safety Updates – January 2023

The RDTC Monthly Formulary Amendments – NICE TA/MHRA Drug Safety Updates – January 2023 plus 30-day NICE TA861 Upadacitinib for treating active non-radiographic axial spondyloarthritis were presented to NTAG to make a recommendation to the NENC Medicines Committee on the formulary status and approval of medicines contained within these documents.

<u>NICE TAs published in January 2023</u>

All ICB-commissioned NICE TAs published in January 2023 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.

Been out for a 4-week consultation via NTAG website:

Had responses from:

- NuTH
- South Tees Trust
- South Tyneside and Sunderland Trust
- Northumbria Trust
- Newcastle place

No respond from:

- Gateshead Trust
- North Tees Trust
- North Cumbria Trust
- CDDFT – no response via consultation form but email from Chief Pharmacist to say “presume that positive NICE will be adopted and started use to ensure compliance with the NHS Constitution.”

Of all the responses received, no barriers raised to implementation by Trusts who responded.

30-day NICE TA861 Upadacitinib for treating active non-radiographic axial spondyloarthritis published 1st Feb 2023

ICB-commissioned NICE TAs 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. The ICB Director of Medicines and Pharmacy has taken action to approve this 30-day TA under his delegated authority.

None of these NICE TAs have been considered by the three existing APCs previously.

Been out for a 2-week consultation via NTAG website:

Had responses from:

- NuTH
- South Tees Trust
- South Tyneside and Sunderland Trust
- Northumbria Trust
- Newcastle place

No respond from:

- Gateshead Trust
- North Tees Trust
- North Cumbria Trust
- CDDFT – no response via consultation form but email from Chief Pharmacist to say "presume that positive NICE will be adopted and started use to ensure compliance with the NHS Constitution."

Of all the responses received, no barriers raised to implementation by Trusts who responded.

All comments received during the two consultations were presented to, and reviewed by, NTAG.

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

All ICB-commissioned NICE TAs published were 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.

NTAG agreed with the suggested formulary status for each drug with a NICE TA published in January 2023 plus 30-day NICE TA861 Upadacitinib for treating active non-radiographic axial spondyloarthritis.

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

10) Formulary applications

Tacalcitol lotion for psoriasis vulgaris

The formulary application from the Medicines Optimisation Team in primary care in County Durham was presented to NTAG. Requested as alternative to calcipotriol on basis tacalcitol is cheaper. Calcipotriol scalp solution is expensive relative to other topical treatments for scalp psoriasis. Tacalcitol lotion is 2.9 times cheaper than calcipotriol. These products have a relatively lower efficacy rank, yet generally higher acquisition cost than products containing topical steroids alone. NENC are the highest prescribers in England of calcipotriol, spending £534,100 pa on single agent calcipotriol.

Published trials of tacalcitol assessed efficacy. When compared with twice daily calcipotriol or calcipotriol/betamethasone treatment, the tacalcitol treatment arm was significantly less effective. NICE guidance suggests topical vitamin D preparation alone only in people who are intolerant of or cannot use topical corticosteroids at this site, or have mild-to-moderate scalp psoriasis.
NTAG agreed to recommend not approving the application on the basis that trial data suggests tacalcitol may not be as effective as calcipotriol.

Trifarotene cream for acne

The formulary application from STHFT was presented to NTAG. Aklief® is indicated for the cutaneous treatment of Acne Vulgaris of the face and/or trunk in patients from 12 years of age and older, when many comedones, papules and pustules are present. Cost effectiveness relative to other treatment options has not been established. Similar price with adapalene on a gram per gram basis. May provide an alternative to unlicensed topical tretinoin preparations which can be expensive. Cheaper than some other options used at the same point in the treatment pathway.
NTAG agreed to recommend approval as a GREEN drug as an alternative to other available retinoids in patients with facial and/or truncal acne, either in combination with other topical therapies, or as monotherapy where a fixed combination product is not tolerated or one component is contraindicated. No cost impact expected.

Ciclosporin 1mg/mL (0.1%) eye drops (Verkazia®) for severe vernal keratoconjunctivitis in children from 4 years of age and adolescents

The formulary application from STHFT was presented to NTAG. Ciclosporin 1mg/mL (0.1%) eye drops (Verkazia®) are the only licensed ciclosporin eye drop for severe vernal keratoconjunctivitis in children from 4 years of age and adolescents.
Currently, a ciclosporin eye drop licensed for another indication in adults is used off-label (unlicensed). Ikervis® is licensed for treatment of severe keratitis in adult patients with dry eye disease which has not improved despite treatment with tear substitutes as a once daily dose.
Noted that prescribers should always try to use a licensed formulation where one is available.
Comments from NuTH on the application were also presented to NTAG.
NTAG agreed to recommend approval as a GREEN+ drug as the only licensed formulation for this indication in this age group and no cost impact expected.

Botulinum toxin for hernia

The formulary application from NuTH was presented to NTAG. Requested for adjunct for closure of complex abdominal wall defects. Low quality evidence from two meta-analyses of cohort/comparative cohort studies suggests that the pre-operative use of botulinum toxin A into the abdominal wall muscles can facilitate fascial closure in abdominal hernia repair. The pre-operative use of botulinum toxin A into the abdominal wall muscles appears to be well tolerated and is less invasive than procedures such as component separation technique (CST) or preoperative progressive pneumoperitoneum (PPP).
The use of botulinum toxin A prior to complex abdominal wall repair is in use in other secondary care Trusts nationally.
Noted that would be an in-tariff drug and an off-label use of the drug. Noted also that this a niche indication with very low patient numbers so difficult to do a randomised controlled trial.
NTAG discussed that due to the low-quality evidence, need to collect some audit data to confirm that has the positive outcomes as suggested in the application.

NTAG agreed to recommend approval as a RED drug as unlicensed and no significant cost impact expected. This would be subject to each Trust approving via their governance routes for unlicensed indications and in tariff hospital-only drugs, plus an audit to taken in a format agreed from the outset by Trust D&Ts to collect outcome data to report back to NTAG in 12 months' time.

Dihydroartemisinin/piperaquine phosphate (Eurartesim®) for malaria

The formulary application from NuTH was presented to NTAG.

The request for dihydroartemisinin/piperaquine phosphate (Eurartesim®) tablets is consistent with current UK and WHO guidelines for the treatment for Plasmodium falciparum malaria.

NTAG agreed to recommend approval as a RED drug and noted that it would only be available at NuTH.

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

11) NENC regional guidance on SGLT2 inhibitors

Following a meeting between the Cardiac, Diabetes and Renal Networks in the NENC, the following existing documents have been combined into one:

- Top Tips and Recommendations for Sodium Glucose Co-transporter 2 inhibitors (SGLT2i) in HFrEF.
- Top Tips and Recommendations for use of Sodium Glucose Co-transporter 2 inhibitors (SGLT2i) in people with Type 2 Diabetes (T2DM) For Glycaemic Control.
- Top Tips and Recommendations for Dapagliflozin [FORXIGA] in Chronic Kidney Disease (CKD).

The content has been clinically checked by the RDTC. Suggested that this document replaces/supersedes the individual Top Tips documents for heart failure, CKD and T2DM.

NTAG agreed to recommend to the NENC Medicines Committee/ICB Executive approval of this updated combined guideline across ICS footprint for consistency in advice for SGLT2 prescribing.

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

12) Dry eyes guideline

A guideline for the treatment of dry eyes that has been developed by South Tyneside and Sunderland was presented to NTAG as a possible basis for developing an NENC guideline. The original intention was that these guidelines would be for South Tyneside and Sunderland use but to also seek approval in County Durham. Sunderland Ophthalmology do not wish to lead on this as regional guideline. There has been no NENC-wide or County Durham consultation on these guidelines.

NTAG received a copy of the review of products that was done by North Tyne the day prior to NTAG and it appears that the brands of products included differ a lot to South Tyneside and Sunderland. Hence do not feel can put the South Tyneside and Sunderland guideline out for wider consultation for ICB adoption at this stage. Doing this without some work done on the product/brand choice would just generate lots of comments and unclear who would be actioning these. NTAG agreed with this.

NTAG liked the format of the ST&S guideline and would be supportive of producing an ICB version provided some consensus can be reached over the product/brand choices in the table. Question from NTAG - is this a priority for the ICB Medicines Team and who would do the work to produce a draft that could go out for consultation across the ICB? The rest of the document seems fine, it is just arriving at a consensus on the brands to include in the table.

The dry eyes section for the formulary has also been identified as one that needs a full review in the next 12-18 months as the ICS moves to single a formulary.

In the interim, suggest that explore trying to get the ST&S guidance approved for local use via the former ST&S APC, and will also share in CD&T to ask CD&T to approve at their May 2023 meeting which is still happening.

13) NENC ICB position statement non-palliative care use of opiates

A single statement on the ICB position on prescribing for persistent pain which will replace the three current APC statements was presented to NTAG. The position statement submitted has been approved by the ICB-wide pain group.

NTAG agreed to recommend to the NENC Medicines Committee/ICB Executive approval of this NENC ICB position statement on non-palliative care use of opiates subject to inclusion of reference to the latest NHS England guidance issued on 2nd March 2023.

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

14) Single ICS formulary – approval

A spreadsheet produced to harmonise the formulary RAG status for those drugs where there is a difference currently across the North East and North Cumbria (NENC) to support the creation of a single NENC ICS formulary was presented to NTAG.

A short life working group of formulary pharmacists from NENC APCs and Trusts, led by the RDTC have reviewed the differences in formulary status and decided on a recommended RAG status. The RED/AMBER/GREEN (RAG) classification offers guidance on the prescribing of drugs initiated in primary and secondary care on the primary basis of patient safety.

No financial impact expected from these changes as RAG changes largely reflect what currently happens in prescribing practice across the majority of the NENC, and analysis of prescribing data has been used to inform some of the changes.

NTAG supported the recommended RAG status for those 2,166 entries where there was no matching RAG status across all three current NENC formularies.

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

15) Regional Medicines Optimisation Committee

Nil this month.

16) APC Decision Summaries

- **CD&T APC January 2023**
- **ST&S APC February 2023**

The committee received in the recent decisions from the three APCs 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.

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

17) Horizon scanning 2023 – RDTC NENC final

NTAG received the Annual Horizon Scanning report for 2023 for information. It noted that the key drugs which will not be considered by NICE are already on a watch list for NTAG.

18) Work plan

The group discussed the work plan.

It agreed to add the following topics:

- NENC DMARD share care guidelines
- Regional menopause guideline
- Formulary applications:
  - Ovamex® injection
  - Otinova® ear spray
- NENC DMARD, Sativex®, and dronedarone share care guidelines
- Regional menopause guideline
- IQoro device
- NENC DOAC decision aid – due review June 2023

19) County Durham & Tees APC minutes – January 2023

Circulated for information.

20) South Tyneside & Sunderland APC minutes – February 2023

Circulated for information.

AOB

NTAG Paliperidone LAI recommendation – updates required

NTAG agreed that following the recent launch of generic paliperidone, LAI to remove brand names from its current NTAG recommendation on paliperidone LAI and update the costings section.

No other business was raised and the meeting concluded.

The date of the next meeting was agreed as 16th May 2023 and will be held virtually via Microsoft Teams.

Minutes produced by G Mankin, Professional Secretary to NTAG, 21st March 2023