Northern Treatment Advisory Group

Minutes of meeting held on the 25th February 2020, 9-12noon

Board Room, The Durham Centre

Present:

- Ian Davidson (ID) Medical Director, North Durham CCG & Chair of NTAG.
- Gavin Mankin (PGM) Principal Pharmacist – Medicines Management, RDTC (professional secretary)
- Matthew Grove (MG) Consultant Rheumatologist, Northumbria Healthcare NHS Foundation Trust.
- Toks Sangowawa (TS) Clinical Advisor/Locum Consultant in Public Health, South Tyneside MBC.
- Nick Timlin (NT) General Medical Practitioner, Hartlepool & Stockton-on-Tees CCG.
- Jill McGrath (JM) Head of Finance, Newcastle Gateshead CCG.
- Alan Bell (AB) Head of Commissioning, Northumberland CCG.
- Ewan Maule (EM) Head of Medicines Optimisation, Sunderland CCG.
- Matthew Lowery (ML) Formulary Pharmacist, Newcastle upon Tyne NHS Foundation Trust
- Andrea Loudon (ALo) Primary Care Development and Medicines Lead, North Cumbria CCG.
- Jim Welch (JW) Patient/Lay Representative

In Attendance: Nil

Apologies were received in advance from: Tim Donaldson, Simon Thomas, Andrew Lloyd, Joe Corrigan, and Siobhan Brown.

The group noted that as apologies from one of the provider representatives had been received the meeting would not be quorate however GM stated that he would run all decisions by the full membership prior to issuing them. *Post meeting Andy Lloyd confirmed in agreement with decisions reached.*

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.

1) Welcome to New Patient/Lay Representative

Jim Welch was welcomed as the new patient/lay representative to NTAG and has been recruited from Durham Healthwatch. A round of introductions was made.

2) Draft Minutes September 2019 Meeting

The group approved the September 2019 minutes.

ACTION: Secretary to publish September 2019 minutes on the NTAG website.

3) Matters Arising

Impact on Secondary Care Prescribing Data of NTAG Recommendations from 2017 to 2018 – been unable to progress further due to concerns from secondary care around sharing of potentially commercially sensitive data. Data though has been received from CNTW on second generation long acting antipsychotics which show they are being used as per NTAG guidance. It was agreed that going forward would explore use of DEFINE to access data and/or approach Trusts for general usage data rather than specific spend data when it was felt there may be an issue with compliance with a particular NTAG recommendation.

4) Appraisal: Liposuction for Lipoedema and Lymphoedema

The updated appraisal report was introduced by the secretary. This had been added to the work plan at the request of the IFR panels due to number of recent of IFRs received. A draft of the report was discussed previously at the June 2019 NTAG meeting.

NTAG members asked for the following further information at the September 2019 NTAG meeting:

- Evidence for using German technique rather than Bronson technique plus any comparison between the two in terms of both clinical and cost-effectiveness – *been unable to find a comparison of the two techniques.*
- Can the specialists tighten the proposed criteria for use? – *RDTC feel these criteria are as narrow as they can be and they mirror closely those used by Dundee.*
- Any information and costs available for other UK providers other than Dundee? – *these have been obtained and costs in Germany plus St Georges in London are approximately equivalent to those from Dundee.*
- How do patients that have been approved via IFR fit the proposed criteria, and what has been their outcome clinically? – *not been able to find this out as yet.*

The following points were raised in discussion:

- Criteria for use particularly around functional ability are still too broad and could impact on functional ability be further defined.
- Most IFRs being received are for lipoedema.
- NICE IPG supports use for lymphoedema but evidence base for lipoedema is weaker.
- NTAG felt some outcome data from those who have had the procedure via IFR would be useful, together with any outcome data from Dundee and St Georges.
- The suggestion of approving for limited time only for limited number of patients referred via one clinic to gather some outcome data was raised.

It was agreed to bring back to the next NTAG meeting for a final discussion with any outcome data that is available, and to discuss with specialists in region tightening criteria for use around functional outcomes.

ACTION: RDTC to seek answers to these questions for next NTAG meeting.

5) Appraisal: Voke® for Nicotine Replacement Therapy

The appraisal report was introduced by the secretary. This had been added to the work plan at the request of public health. There have been no specific requests for it by specialists.

Voke 0.45 mg Inhaler is a new delivery form of Nicotine Replacement Therapy (NRT), licensed by the MHRA, as a safer alternative to smoking. It is designed to look, feel and be used in a way that captures many of the elements of smoking - such as removing from the pack, putting it in the mouth, inhaling and exhaling. Voke is not an e-cigarette, instead it is the world's first propellant nicotine inhaler which delivers nicotine into the arterial bloodstream, purporting to closely mimic the nicotine delivery from traditional cigarette smoking and providing rapid craving relief. It produces no heat, no burn, and no vapour, yet mimics the smoking rituals which are important to some smokers.

No further efficacy studies were conducted, but some pharmacodynamic measures regarding cravings were included in one pharmacokinetic study. This study consisted of four parts (A-D), two assessing Voke inhaler alone (n=18, Part A, and n=18, Part C), and two assessing Voke inhaler versus the reference product, Nicorette 10 mg® Inhalator (n=24, Part B, n=24, Part D). This study did not include any evidence for effectiveness in smoking cessation (i.e. reduction of smoked cigarettes).

Voke is a hybrid product therapeutically equivalent to the reference product Nicorette 10 mg Inhalator. There was a lack of bioequivalence between products. However, Voke pharmacokinetic profile was qualitatively closer to that of a cigarette, although with lower absolute nicotine concentrations. Also, craving relief was generally greater for Voke device than for Nicorette 10 mg Inhalator. Voke was well tolerated and its safety profile was similar to Nicorette Inhalator and consistent with other forms of NRT.

There is a large body of literature on NRT for smoking cessation, but very limited data is available regarding the specific efficacy of nicotine inhalers. Two recent Cochrane reviews found that the form of nicotine delivery of NRTs is unrelated to effectiveness, and that evidence to date favours the use of combination versus single NRT form. There are limited studies assessing the efficacy on smoking cessation of NRTs versus E-cigarettes, as well as in particular populations, such as pregnant women.

Regarding special populations, Voke is indicated in pregnant and lactating women making a quit attempt, although specific studies for this population have not been performed.

Cost of treatment cannot be easily compared with other NRT, since dosage differs widely between forms and most are used in combination. Price per equivalent cigarettes is likely to be more expensive than for E-cigarettes that are not licensed as medicinal products.

It was agreed that more rigorous data showing the benefits of Voke® as a stop smoking aid must be available prior to being approved for use on the NHS and for GP prescribing.

ACTION: Secretary to draft recommendation as above.

6) Pitolisant Audit Data

Pitolisant approved as RED drug by NTAG in Nov 2018 with an agreed pathway and it was also agreed that prospective data would be collected about the use of this medication in each centre over the period of the following 12 months as a part of the audit cycle and submitted to NTAG to provide evidence for safety and potential cost efficacy. It would also monitor adherence to prescription guidelines.

The data received from the RVI and James Cook was presented to the meeting and shows that the drug is being used as per the NTAG recommendation. Primary care prescribing data shows not being prescribed in primary care with a few individual patient exceptions, demonstrating that the hospital only status is being adhered to.

It was noted that RMOC is also currently preparing a national position statement on the use Pitolisant.

7) Review of NTAG recommendation on Sodium oxybate (Xyrem®) in the management of narcolepsy with cataplexy in adult patients in light of RMOC position statement atiromer for hyperkalaemia

The new national guidance from RMOC on the commissioning of sodium oxybate in adults patients with narcolepsy with cataplexy was brought to the attention of NTAG by the secretary. It was suggested that NTAG consider revising its current recommendation on the use of Sodium oxybate (Xyrem®) in adult patients in light of new national guidance from RMOC, and this has the support of local clinicians at the RVI and James Cook.

The current NTAG recommendation from June 2017 matches the RMOC guidance for use in children and adults receiving sodium oxybate as a child. But currently NTAG do not recommend use in adults who have not received sodium oxybate as a child. RMOC has suggested some criteria for potentially eligible patients for CCGs to consider funding and commissioning use in this group of sodium oxybate treatment naïve adult patients.

The RMOC statement does not stipulate that sodium oxybate must be commissioned, but aims to assist the decision making process and improve consistency. It was felt that the RMOC statement does not really address the issue of cost-effectiveness.

The RMOC statement 2019 has referenced 5 additional studies for the use of sodium oxybate in narcolepsy with cataplexy that were not included in the 2017 NTAG review. However none of these are randomised controlled trials (RCTs) and all provided results consistent with the already established evidence base. Three of these are only available as conference abstracts and cannot be fully appraised. None of the additional evidence adds to the cost-effectiveness evidence base for sodium oxybate.

Elsewhere in England pathways available from SE London and Pan Mersey include use of sodium oxybate in treatment naïve adults as 4th line option after pitolisant.

NTAG noted that a generic of sodium oxybate is expected shortly and this will change the cost-effectiveness of the drug. It may also change the positioning of sodium oxybate in clinical pathways on the basis of cost.

After discussion NTAG agreed to make no change to its current recommendation but to review if and when further information is available on the availability of generic sodium oxybate, particularly in relation to cost effectiveness compared to other treatment options.

8) Review of NTAG position on bezlotoxumab for C.difficile in light of terminated NICE appraisal

NTAG agreed previously in February 2018 not to issue a recommendation until further guidance from NICE/PHE on place in therapy available as there was no appetite from specialists within the region to use at that stage.

Since then NICE has been unable to make a recommendation on bezlotoxumab (Zinplava) for preventing recurrent Clostridium difficile infection in adults because the manufacturer did not provide an evidence submission.

It is a CCG commissioned tariff-excluded drug.

NTAG discussed the need to issue a regional recommendation on use of the drug as NICE does not intend to. It was agreed based on feedback from regional specialists that formal recommendation is not needed but hospitals can submit an individual patient funding request to CCG on case by case basis if they wish to use.

NTAG noted that NICE intend to update their clinical guidelines on management of C.difficile including place in therapy of fidaxomicin and bezlotoxumab but no timescales available for this.

9) Review of NTAG position on Sativex for non-MS pain in light of new NICE Guidance

NTAG discussed and agreed to update its current recommendation on the use of Sativex for non-MS pain in light of new NICE Guidance. This does not change the recommendation itself but will make reference to NICE NG144: Cannabis-based medicinal products, November 2019.

NICE makes the following recommendation:

1.2 Chronic pain

1.2.1 Do not offer the following to manage chronic pain in adults:

- nabilone
- dronabinol
- THC (delta-9-tetrahydrocannabinol)
- a combination of cannabidiol (CBD) with THC.

1.2.2 Do not offer CBD to manage chronic pain in adults unless as part of a clinical trial.

ACTION: Secretary to draft recommendation as above.

10) Review of NTAG recommendation: Lycra Garments for the management of cerebral palsy and other neurological or musculoskeletal conditions

NTAG was made of aware and discussed correspondence received from DM Orthotics (one of manufacturers) by NECS with reference to North Durham/DDES CCG commissioning position for Lycra Garments for the management of cerebral palsy and other neurological or musculoskeletal conditions. This correspondence has not been directly received by NTAG itself from the manufacturer.

NTAG reviewed Lycra Garments for the management of cerebral palsy and other neurological or musculoskeletal conditions in February 2017 and September 2018 and did not recommend use. The group was concerned about paucity of evidence for efficacy for the use of Lycra garments. It instead suggested some criteria instead to be used by IFR panels to assist requests.

The RDTC looked for new clinical evidence since September 2018. Since the original NTAG review, there have been some developments in the study of the use of Lycra orthoses particularly for the management of cerebral palsy. Key publications since the original review investigating use of Lycra orthoses for cerebral palsy include three systematic reviews and one RCT published as two publications looking at different outcome measures. A non-randomised controlled study was also published. Nothing found that RDTC believe would result in a change to the conclusion of the previous review

NTAG noted that the IFR team have drafted a response to inform the manufacturer that no change to approach to process Lycra requests and there is nothing stopping clinicians them applying on individual patient basis and being assessed on exceptionality.

After discussion NTAG agreed not no review of the current NTAG recommendation was required because no formal appeal has been received as per the NTAG appeals policy.

11) Review of NTAG recommendation: Gammacore for Cluster Headache in light of new NICE Guidance

NTAG discussed and agreed to update its current recommendation on the use of non-invasive transcutaneous vagus nerve stimulation (gammaCore) to include reference to the NICE Medical technologies guidance [MTG46] published in December 2019

Update current NTAG recommendation for Gammacore will be updated as follows:

- Cluster headache – recommended as per NICE Medical technologies guidance [MTG46]
- Migraine – no change to current NTAG recommendation not to not recommend the use of non-invasive transcutaneous vagus nerve stimulation for the treatment of migraine. This is because NICE makes no recommendation on use this group of patients.

ACTION: Secretary to draft recommendation as above.

12) Regional Medicines Optimisation Committee

- **RMOC Operating Model 2010** – circulated for information.

- **RMOC Advisory Statement: Sequential Use of Biologic Medicines** – NTAG noted this statement and that is has one relevant recommendation around the sequential use of biologics to treat psoriatic arthritis which complies with this advisory statement from RMOC.

A verbal update on the Regional Medicines Optimisation Committees was given to the group. Their workplan and agendas can be found on the Specialist Pharmacy Services website.

13) NTAG Membership

a) Secondary Care vacancies

Following the last NTAG meeting the North East & Cumbria Chief Pharmacists network have been approached again to seek a new provider Trust representative to attend NTAG but no response has been received as yet. It was agreed to approach South Tyneside and Sunderland NHS Foundation Trust once more to see if they would like to take up the vacancy.

ACTION: EM to approach formulary pharmacist at City Hospitals Sunderland

b) Primary care medicines vacancies

No further progress has been made.

ACTION: NT to identify deputy GP representative from Tees Valley CCG.

ACTION: ID to identify deputy GP representative from Durham CCG.

14) NTAG Recommendations to Review or Archive

NTAG noted that current following NTAG recommendations will be archived once superseded by NICE TA.

- Erenumab – NICE FAD subject to appeal
- Liraglutide for obesity – NICE TA due March 2020
- Patiromer for hyperkalaemia – NICE issued Feb 2020 recommending use.

15) Horizon Scanning

A summary new drugs falling into potentially into NTAG remit in next 12-18th months circulated for information. This is based on the national Prescribing Outlook publication.

16) Work Plan.

The group discussed the work plan.

- Buprenorphine long acting injection (Buvidal®) – has been referred to RMOC South and so advised to wait to see what further guidance is issued nationally by them plus timescales for this.
- New drugs for wAMD – NICE TA date to TBC – to watch for developments before considering adding to workplan.

- Dupilumab and Omalizumab for chronic rhinosinitis with nasal polyps – added to Sept 2020 NTAG agenda provisionally as no NICE TA not expected until July 2021.
- Diveen for female urinary stress incontinence - added to June 2020 NTAG agenda.
- Contiform for female urinary stress incontinence - added to June 2020 NTAG agenda.
- Purewick female external urinary catheter – added to June 2020 NTAG agenda.
- SGLT2 in three diabetic cohorts – ASCVD, Heart failure and CKD – currently being considered for workplan
- Inhaled levodopa for Parkinson's disease – not in in NICE workplan. Added to Sept 2020 NTAG agenda provisionally.
- Verteporfin photodynamic therapy for chronic central serous chorioretinopathy – review of current NTAG recommendation as new guidance and trial data available. Prioritised for June 2020 NTAG.
- Review of NTAG recommendations >2 years old – agreed to review need to review all current NTAG recommendation at June 2020 NTAG meeting and then start scheduling into workplan as required in order of priority and/or age.
- Semaglutide oral – first oral GLP1 and no currently in NICE workplan. Agreed to add to workplan for Sept 2020 NTAG
- Infliximab subcutaneous – no separate NICE appraisal other than that for IV formulation expected so agreed to add to workplan for June 2020 or Sept 2020 NTAG.
- Andexanet alfa – review current NTAG recommendation if clinicians submit regional pathway/criteria for use but noted NICE TA now due in June 2020 which will supersede current NTAG recommendation.
- Sufentanil (Duzevo®) – agreed to remove from workplan as still no firm launch date in the UK available.

17) Impact on Primary Care Prescribing Data of NTAG Recommendations from 2017, 2018 and 2019

Data on number of items/spend in each stakeholder CCG on NTAG recommendations from 2017 to 2018 having an impact on primary care prescribing presented for to the group for information. This shows that NTAG recommendations are largely being adhered to in primary care.

ACTION: Secretary to share primary care data with stakeholder CCG Medicines Optimisation Teams

18) AOB

Nil

No other business was raised and the meeting concluded.

The date of the next meeting was agreed to be 2nd June 2020

Minutes produced by G Mankin, Professional Secretary to NTAG, 25th February 2020