Northern Treatment Advisory Group

Minutes of meeting held on the 8th December 2020, 9-10.15am

Virtual Online Meeting via Microsoft Teams

Present:

- Ian Davidson (ID) Medical Director, County 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.
- Siobhan Brown (SB), Chief Operating Officer, Northumberland CCG.
- Jill McGrath (JM) Head of Finance, Newcastle Gateshead CCG.
- Ewan Maule (EM) Head of Medicines Optimisation, Sunderland CCG.
- Ian Morris (IM) Senior Clinical Services Manager, NECS
- Simon Thomas (ST) Consultant Physician, Newcastle upon Tyne NHS Foundation Trust
- Robert Lapham (RL) Formulary Pharmacist, South Tyneside & Sunderland NHS Foundation Trust.
- Andrew Lloyd (AL) Consultant Anaesthetist and Chair of South Tees D&T, The James Cook University Hospital (JCUH).
- Jim Welch (JW) Patient/Lay Representative.

In Attendance:
Rachel Perry – Public Health Registrar, South Tyneside Council – observing.
Gayle Thorpe – GP, County Durham CCG – observing – new deputy for Ian Davidson on NTAG.

Apologies were received from: Claire Sands, Tim Donaldson, Nick Timlin, Helena Gregory, Matthew Lowery

The meeting was quorate.

No declarations were received prior to the meeting on receipt of the agenda and when the Chair invited any declarations of interests Andy Lloyd declared an indirect interest through his private practice relating to Item 5. It was agreed as he was not actually the prescriber of these drugs and hence was had an indirect interest that could take full part in the agenda item.

1) Draft Minutes September 2020 Meeting

The group approved the September 2020 minutes.

ACTION: Secretary to publish September 2020 minutes on the NTAG website.

2) Matters Arising

- Review of NTAG recommendation on Sodium oxybate (Xyrem®) in the management of narcolepsy with cataplexy in adult patients in light of RMOC position statement - awaiting

RMOC statement on Pitolisant before progressing as may change place in therapy and costings now generic Sodium oxybate available.

- Review of NTAG recommendation – Liraglutide for obesity – will be superseded by NICE TA due on 9th December 2020 and so the current NTAG recommendation will be archived.
- Review of NTAG recommendations relating to the eye – awaiting feedback from NE Retina Group as to which recommendations require review.
- Cost Modelling of Type 2 Diabetes Medicines (e.g. SGLT2, GLP-1s) in ASCVD, Heart Failure and CKD – joint letter sent with GMMMG to NICE asking them to expedite their guidance review. NICE responded to say will be updating their workplan at end of November 2020 and will take this into consideration.
- Oral Semaglutide – NTAG noted that South Tyneside & Sunderland APC had not approved the NTAG recommendation relating to oral semaglutide agreed at the September 2020 NTAG meeting. This was due to financial concerns expressed by the Trust rather than the CCG. The concern was the recommendation may lead to use of oral semaglutide earlier in treatment pathway as it as an oral preparation as opposed to an injection. The APC is currently working through these concerns as part of the wider work around reviewing current type 2 diabetes pathways in relation to earlier use of agents with proven cardiovascular outcomes.

3) Appraisal: Solriamfetol for Narcolepsy

The appraisal report was introduced by the secretary. This had been added to the work plan via horizon scanning. The drug is launched in the UK and the associated NICE TA has no expected date of publication. It is a CCG commissioned tariff excluded drug.

Solriamfetol is a dopamine and noradrenaline reuptake inhibitor, but the mechanism of effect in narcolepsy is not fully known. It is licensed at a dose of 75 mg or 150 mg daily to improve wakefulness and reduce excessive daytime sleepiness (EDS) in adults with narcolepsy with or without cataplexy.

It offers an additional option for the treatment of narcolepsy and would potentially be used after modafinil as an alternative to pitolisant or sodium oxybate.

In a phase III trial, solriamfetol produced significant improvements in EDS and sleep latency times compared to placebo. There were no significant improvements in quality of life at the licensed doses, as measured by the Functional Outcomes of Sleep Questionnaire 10 item version. The trial was small, with less than 60 participants per arm, and short (12 weeks). This is comparable in size to the trials for pitolisant.

An open label safety study enrolled participants who had previously completed a clinical trial of solriamfetol for narcolepsy or OSA. The study suggested that improvements in EDS were largely maintained over the 40-52 week treatment period.

There are no studies comparing solriamfetol to active comparators, meaning there is no evidence on how it compares to other more established treatment. Similarly the published papers give no information on past treatments, so it is not clear whether patients who have previously failed treatment with other medicines have comparable outcomes.

Requiring patients to stop all other medicines for narcolepsy means there is no data on interactions between solriamfetol and these medicines, which may have implications for clinical practice.

NTAG reviewed the available safety data in particular around cardiovascular safety. The most commonly reported AEs were headache, nausea, decreased appetite, and anxiety. Cardiovascular events were more common with solriamfetol than placebo, but this effect appears to be restricted to patients with OSA.

The cost impact of introducing solriamfetol will depend on the proposed place in therapy. But it is cheaper than using pitolisant.

The group noted that NICE is due to issue a technology appraisal for Solriamfetol for the treatment of narcolepsy which when issued will supersede this NTAG recommendation.

The views of regional specialists were also presented to NTAG.

After discussion NTAG agreed to recommend the use of Solriamfetol for the treatment of narcolepsy with or without cataplexy in adults as an alternative to Pilolisant in those who would have otherwise received Pitolisant. Prescription of this medication will be limited to Sleep Centres with adequate expertise in managing narcolepsy and using this medication: The James Cook University Hospital, Department of Sleep Medicine and Royal Victoria Infirmary. And to be used in line with an agreed regional pathway for the management of narcolepsy. In the absence of clear and objective improvement in narcolepsy then solrimafetol should be discontinued. This recommendation does not support the use of solrimafetol in combination regimens.

ACTION: Secretary to draft recommendation as above.

4) Appraisal: Solriamfetol for obstructive sleep apnoea

The appraisal report was introduced by the secretary. This had been added to the work plan via horizon scanning. The drug is launched in the UK and the associated NICE TA has no expected date of publication. It is a CCG commissioned tariff excluded drug.

Solriamfetol is a dopamine and noradrenaline reuptake inhibitor, but the mechanism of effect in obstructive sleep apnoea (OSA) is not fully known. It is licensed at a dose of 37.5 mg, 75 mg or 150 mg daily to improve wakefulness and reduce excessive daytime sleepiness in adult patients with OSA whose sleepiness has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP).

Solriamfetol was assessed in two phase III efficacy trials and one safety trial. TONES-3 found that solriamfetol treatment resulted in significant improvements in mean sleep latency time (MSLT) and Epworth sleepiness scale (ESS) scores compared to placebo. No minimum clinically important difference (MCID) has been established for the MSLT. Patients in all groups exceeded the MCID for the ESS, including those who received placebo.

There are no other licensed pharmacological options for sleepiness associated with OSA, so there are no comparisons available. Solriamfetol appears to result in significant improvements in EDS symptom scores, but these do not always translate to improvements in quality of life.

After discussion NTAG agreed that is does not currently recommend the use of Solrimafetol for obstructive sleep apnoea adults

This recommendation was made taking into account the views of local clinicians because:

- NTAG felt solrimafetol offered no clinical or cost advantage over current treatment options for obstructive sleep apnoea to use ahead of a NICE technology appraisal being issued.
- Concerns around safety (in particular cardiovascular safety) in this patient group.

The group noted that NICE is due to issue a technology appraisal for Solrimafetol for obstructive sleep apnoea which when issued will supersede this NTAG recommendation.

ACTION: Secretary to draft recommendation as above.

5) Appraisal: Dupilumab and Omalizumab for Chronic Rhinosinitis with Nasal Polyps

The appraisal report was introduced by the secretary. This had been added to the work plan via horizon scanning. It is a CCG commissioned tariff excluded drug.
The NICE TA for omalizumab has been delayed due to COVID-19, with no new date of expected publication.
The NICE TA for dupilumab was terminated in September 2020 because the manufacturer did not provide an evidence submission. The company has confirmed that it does not intend to make a submission for the appraisal because there is unlikely to be sufficient evidence that the technology is a cost-effective use of NHS resources in this population.

The effectiveness of omalizumab and dupilumab in preventing or reducing the need for surgery is yet to be clearly established. Additional, large-scale studies are needed to confirm whether biologics represent a valid alternative to primary or revision sinus surgery.

Also no published economic analyses on the use of omalizumab or dupilumab in the treatment of Chronic Rhinosinitis with Nasal Polyps (CRSwNP) were identified.

The group noted that NICE is due to issue a technology appraisal for omalizumab in the treatment of CRSwNP which when issued will supersede this NTAG recommendation.

After discussion NTAG agreed not to recommend the use of Dupilumab or Omalizumab for chronic rhinosinitis with nasal polyps (CRSwNP).

ACTION: Secretary to draft recommendation as above.

6) Review of Current NTAG Recommendation for Stand-alone minimally invasive surgical bipolar radiofrequency ablation for atrial fibrillation

NTAG reviewed the current NTAG recommendation from April 2016 for Stand-alone minimally invasive surgical bipolar radiofrequency ablation for atrial fibrillation. No new evidence or guidance has been found to change the current NTAG recommendation.

NTAG agreed to add a statement to current recommendation to say reviewed evidence based in December 2020 and found no evidence to support changing the current recommendation.

ACTION: Secretary to update recommendation as above.

7) Review of Current NTAG Recommendation for Daily vs on-demand PDE-5 inhibitors for management of erectile dysfunction following treatment for prostate cancer

NTAG reviewed the current NTAG recommendation from February 2018 for Daily vs on-demand PDE-5 inhibitors for management of erectile dysfunction following treatment for prostate cancer. No new evidence or guidance has been found to change the current NTAG recommendation.

NTAG agreed to add a statement to current recommendation to say reviewed evidence based in December 2020 and found no evidence to support changing the current recommendation.

ACTION: Secretary to update recommendation as above.

8) Impact on Primary Prescribing Data of NTAG Recommendations from 2017-2020

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.

9) Regional Medicines Optimisation Committee

Nothing to update. Their work plan and agendas can be found on the Specialist Pharmacy Services website.

10) 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. Guidance was expected in May 2020 but delayed due to COVID-19.
- Andexanet alfa – review current NTAG recommendation if clinicians submit regional pathway/criteria for use but noted NICE TA in progress which will supersede current NTAG recommendation.
- Perampanel (Fycompa®) for Partial-onset (focal) epilepsy - review of current recommendation from Nov 2012 to reflect latest license extension.
- Melatonin (subject to confirmation & views of Mental Health reps to NTAG) - Review of evidence of base for each indication. Plus guidance on need for review when transitioning from adolescence to adulthood

11) Review of Current NTAG Terms of Reference and Membership

The group reviewed the NTAG Terms of Reference which were last updated in November 2018 and agreed to defer the review until the next NTAG meeting when more might be known about the changes to primary care management structures from April 2022.

12) NTAG Meeting Dates for 2021

Circulated for information. Meetings will be cancelled if there are no agenda items or appraisals to consider for that particular meeting.

13) Biosimilar Teriparatide

A request has been received from NECS for NTAG to consider issuing a similar statement to that available from GMMMG around the use of biosimilar teriparatide for the treatment of osteoporosis in postmenopausal women as per NICE TA161.

NTAG discussed and agreed to issue a statement supporting use of cheaper biosimilar brands of teriparatide for the treatment of osteoporosis in postmenopausal women.

ACTION: Secretary to draft recommendation as above.

14) Flash Glucose Monitoring for People with Learning Disability and Diabetes

A new additional criteria has been added to the NHS England Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patient. This is:

- People with Type 1 diabetes or insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register.

NTAG discussed and agreed that the decision to start Flash Glucose Monitoring for this new criteria should be as for all other previously agreed criteria should only be made by the diabetes specialist for an initial 6 month trial period. The specialist will write to patent's GP practice requesting that they continue to prescribe and confirm patient meets criteria for initiation.

NTAG agreed to update its current Flash Glucose Monitoring recommendation from 16th April 2019 (amended June 2019) to include the new learning disability and on insulin criteria.

ACTION: Secretary to update recommendation as above.

15) AOB

No other business was raised and the meeting concluded.

The date of the next meeting was agreed to be 23rd February 2021 and will be held virtually via MicrosoftTeams.

Minutes produced by G Mankin, Professional Secretary to NTAG, 8th December 2020