Northern Treatment Advisory Group

# Minutes of meeting held on the 20th November 2018, 9-12am,

# Meeting Room 4, 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)
- Andrew Lloyd (AL) Consultant Anaesthetist and Chair of South Tees D&T, The James Cook University Hospital (JCUH)
- 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.
- Matthew Lowery (ML) Formulary Pharmacist, Newcastle upon Tyne NHS Foundation Trust
- Jill McGrath (JM), Head of Finance, Newcastle Gateshead CCG
- Siobhan Brown (SB), Chief Operating Officer, Northumberland CCG
- Ian Morris (IM), Senior Clinical Services Manager, NECS

In Attendance: Nil

Apologies were received in advance from: Tim Donaldson, Joe Corrigan, Ewan Maule, Andrea Loudon, Simon Thomas

The meeting was quorate.

No declarations of interest were received or declared.

## 1) Draft Minutes September 2018 Meeting

The group approved the September 2018 minutes.

**ACTION: Secretary to publish September 2018 minutes on the NTAG website.**

## 2) Matters Arising

Pitolisant – the group noted that following the discussions at the September 2018 NTAG meeting that use of pitolisant had now been approved by Chair's action now that the supporting pathway and place in therapy had been agreed with the clinicians.

Freestyle Libre – NTAG noted the recent announcement by NHS England that Freestyle Libre is to be made available on prescription from GPs or diabetes team for all patients who qualify for it in line with NHS clinical guidelines as of 1st April 2019. Clarity is being sought by NHS Clinical Commissioners on how this will be funded and which NHS Clinical Guidelines this be based upon.

## 3) Appraisal: Erenumab and galcanezumab for prophylaxis of migraine

The appraisal report was introduced by the secretary. This had been added to the work plan via horizon scanning.

A new class of monoclonal antibodies specific for CGRP (a neuropeptide involved in pain signalling) has been developed for the prophylaxis of migraine. One of these (erenumab) has been launched while a second (galcanezumab) has been given a positive opinion by the CHMP of the EMA. Two more (fremanezumab and eptinezumab) are expected to launch in the next 1-3 years.

The likely target population for CGRP-specific antibodies is patients with significant disease burden despite standard care with the currently-available options. Current management of these patients will vary depending on their migraine subtype:

- Episodic migraine: oral preventive medicines, with or without acute treatments
- Chronic migraine: Botox every 12 weeks, with or without oral preventives and acute treatments.

Due to the design of the clinical trials it is not clear to what degree these existing treatments would be displaced if anti-CGRP antibodies were to be introduced.

The bulk of the clinical trial data comes from studies with low proportions of patients with previous use of preventive medicines. Patients with recent use of Botox were excluded entirely. The LIBERTY trial compared erenumab 140 mg to placebo in patients with previous failure of 2-4 prophylactic treatments. It showed a treatment effect, but a smaller proportion of patients achieved ≥50% reduction in migraine days than in the ARISE & STRIVE trials. This implies that patients with previous treatment failures may require the higher licensed dose of 140 mg every four weeks to receive benefit from treatment.

Erenumab may be more acceptable to patients than Botox, since it can be self-administered as a single injection each 4 weeks. By contrast Botox requires attendance at clinic every 3 months, and each treatment consists of multiple injections.

The trial data on impact on quality of life are useful, but do not capture all of the relevant information. For example, it is not clear whether a patient with no reduction in number of migraine days or attacks may yet derive benefit in terms of reduced severity of symptoms. Data on headache intensity were collected as an exploratory endpoint in the erenumab trials, but not presented in any publication.

Galcanezumab is licensed for prophylaxis of migraine in people with ≥4 migraine days per month, but there are no published data for people with chronic migraine (≥15 headache days per month). Two 6 month trials in people with episodic migraine found that galcanezumab reduced the mean number of migraine days by roughly 5 days, compared to roughly 3 days for placebo. The treatment effect was similar irrespective of galcanezumab dose. Limitations were similar to those highlighted for erenumab.

Most adverse events with erenumab were of mild-moderate severity, and there were few differences between placebo and active treatment groups. Some evidence suggests that erenumab may lead to increases in systolic and diastolic blood pressure, but the overall cardiovascular safety profile is not clear. The EMA has requested additional studies.

Adverse event rates were similar between galcanezumab and placebo, with the main difference being injection site reactions. There was no difference in serious adverse events.

The NHS list price of erenumab is £386.50 for one pre-filled pen, each containing a single 70 mg dose. The total annual cost would therefore be £5,024.50 per patient (70 mg Q4W) or £10,049 (140 mg Q4W). It is not known whether any commercial agreements are planned to reduce the cost. Erenumab is intended for self-administration. The price for galcanezumab is not yet available but is expected to be similar. For comparison, the most costly option for prophylaxis currently in routine use is Botox, which is licensed in chronic migraine only. Treatment is required once every 3 months, at a dose of around 155-195 units per administration. Botox 200 units costs £276.40 per vial (totalling £1,106 per year) and is not tariff excluded for this indication. The cost of an outpatient neurology attendance is estimated at £116- 135 (2018/19 National Tariff, non-mandatory price for outpatient attendance with single or multiple professionals).

In the UK 2 years of erenumab treatment will cost £10,049-£20,098, depending on dose. Based on data from this study the incremental cost-effectiveness ratio for the UK is therefore an estimated £54,348 to £108,697 per QALY gained. This estimate is highly dependent on the NHS price of erenumab, and does not take into account any discounts or patient access schemes, reductions in use of other healthcare resources (e.g. acute treatments, emergency care, etc.), or losses due to reduced productivity associated with migraine. The ICER compared to continuing prophylactic treatment is likely to be higher, but can't be quantified.

NICE technology appraisals of erenumab and fremanezumab are planned, but the expected publication dates are not yet available but estimated to be in the 3rd quarter of 2018. Galcanezumab and eptinezumab were not in the NICE workplan at time of writing.

**The group agreed not to recommend the use of Erenumab and galcanezumab for prophylaxis of migraine. The group was concerned about the cost-effectiveness, clinical trials to date included a low proportion of patients with previous use of preventive medicines, lack of clinical trial evidence comparing with other treatment options for migraine, and the current lack of long term safety data. Patients with recent use of botulinum toxin were also excluded entirely from published trials to date.**

**ACTION: Secretary to draft recommendation as above.**

## 4) Appraisal: Actipatch® for the management of localised musculoskeletal pain

The appraisal report was introduced by the secretary. This had been added to the work plan via horizon scanning.

ActiPatch® is a wearable pulsed electromagnetic field device for the management of localised musculoskeletal pain. Three versions of the ActiPatch® device are available, with each product specifically tailored for the treatment of knee pain, back pain or muscle and joint pain. Each device has an on/off function and lasts for 720 hours. All three products can be purchased without prescription online and OTC at a retail cost of £20 to £25 per device. A refill device, supplied without any attachments is available for £20. The device was recently added to the NHS Drug Tariff at a cost of £13.95 for each of the three products.

In a small RCT in patients with osteoarthritis of the knee (n=60), one month of treatment with the ActiPatch® device was associated with a reduction in VAS pain and WOMAC score compared with placebo.

A registry study evaluated efficacy of the device in subjects with chronic musculoskeletal pain due to a variety of aetiologies. After using a trial device for seven days, 65% of subjects reported a benefit from the trial device, with an average pain reduction in these individuals of 57%. A three month follow-up survey showed sustained pain relief; decreased analgesic use and improved QoL. In a second registry study in subjects with chronic back pain, 52% of subjects reported a benefit from the trial device, with a mean pain reduction of 66%. Over the same period, 36% of subjects had a decrease in their medication use, and 14% stopped using pain medications. Due to the limitations of the registry design, the self-selected enrolment and self-reported nature of data collection, and the lack of a control group these findings should be interpreted with caution.

There are no RCTs comparing the efficacy of ActiPatch® in comparison to other non-pharmacological interventions for chronic pain. Also the the long term safety and efficacy of the ActiPatch® is unknown.

**The group agreed not to recommend the use of Actipatch® for management of localised musculoskeletal pain on the NHS. Should patients wish to use the device it can be purchased over the counter. The group was concerned that the current published clinical evidence was not sufficient to demonstrate the product's efficacy, and evidence from high quality randomised controlled trials was lacking. There are no RCTs comparing the efficacy of Actipatch® with other pharmacological or non-pharmacological interventions for localised musculoskeletal pain.**

| **ACTION: Secretary to draft recommendation as above.** |
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## 5) Regional Medicines Optimisation Committee

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.

The group noted that it may need to review its recommendation from June 2017 on Sodium Oxybate for Narcolepsy in Adults in light of imminent guidance due from RMOC Midlands & East.

## 6) NTAG Terms of Reference – review

The group reviewed the NTAG Terms of Reference which were last updated in September 2017.

It was agreed to make the following changes:

- Change references to Northern CCG Forum to Northern CCG Joint Committee to reflect changes in structure regionally.
- Remove reference to Northern Clinical Senate.
- Update geography covered by NTAG to include North Cumbria CCG and Hambleton, Whitby & Richmondshire CCG.

- Make reference to NTAG role to be the route for adoption of RMOC new drug recommendation regionally as agreed by the December 2017 Regional CCG Forum.

NTAG discussed the need for confirmation and clarity on its accountability arrangements in light of changing NHS structures and accountability/decision making processes within the region. It also felt the need to seek the view of the Northern CCG Joint Committee was to whether there was still a place and role for NTAG in light of the creation of Regional Medicines Optimisation Committees, and if so some clarity on the remit of NTAG.

**ACTION:**
**ID/GM to take NTAG Terms of Reference to Northern CCG Joint Committee for approval and seek their view on remit, role and need for NTAG together with confirmation of accountability arrangements.**

## 7) NTAG Membership

### a) Secondary Care vacancies

Following the last NTAG meeting the North East & Cumbria Chief Pharmacists Network have been approached to seek a new provider Trust representative to attend NTAG but no response has been received as yet.

### b) Primary care medicines vacancies

The group also discussed the need for named deputies for the current GP representatives to NTAG. All other primary care NTAG membership vacancies have now been filled.

**ACTION:**
**Secretary to contact North East & Cumbria Chief Pharmacists Network to continue to seek one new provider Trust representative to attend NTAG.**

**ID/GM to write to stakeholder CCGs to seek a named deputy for the current GP representatives to NTAG.**

## 8) Work Plan.

The group discussed the work plan.

It was agreed to add the following to the workplan for the February 2019 meeting:

- Doxylamine/Pyridoxine (Xonvea®) – Identified via horizon scanning. First licensed medicine for N&V in pregnancy. Potential cost impact = £158,400 (worst case) which is 3x NTAG Threshold for considering a drug. Also agreed use should be equitable across NE&C.
- i-Port Advance – request to consider from Diabetes Network. Medical device for use in children & adults which allows multiple subcutaneous injections for 3 days (or 75 injections) without having to puncture the skin for each dose of medication. There have been a number of IFR requests submitted across the region. Noted it is not currently listed in the Drug Tariff.

- Medical Cannabis for CCG commissioned indications – request from North Cumbria CCG. Noted that patient interest in this topic is high. NICE guidance expected Oct 2019 until then RED drug per NHSE letter.

The following topic has been put on hold:

- Sufentanil (Duzevo®) – licensed for acute to moderate severe pain - awaiting UK distributor and UK launch date.

It was agreed to seek the views of regional cardiologists before proceeding with a NTAG review for Rivaroxaban in combination with aspirin for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events.

## 9) NTAG Meeting Dates 2019

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

## 10) AOB

Nil

No other business was raised and the meeting concluded.

The date of the next meeting was agreed to be 26th February 2019.

*Minutes produced by G Mankin, Professional Secretary to NTAG, 20th November 2018*