Northern Treatment Advisory Group

Minutes of meeting held on the 4th September 2018, 9-12am,

Morrison Trust, Morton Park Business Training Centre, Yarm Road, Darlington DL1 4PJ

Present:

- Ian Davidson (ID) Director of Quality and Safety, North Durham CCG & Chair of NTAG.
- Gavin Mankin (PGM) Principal Pharmacist – Medicines Management, RDTC (professional secretary)
- Nicola Bailey (NB) Chief Officer, North Durham CCG & DDES CCG
- Claire Sands (CS) Assistant Head of Finance, Newcastle Gateshead CCG.
- Andrea Loudon (ALo) Primary Care Development and Medicines Lead, North Cumbria CCG.
- Ewan Maule (EM) Head of Medicines Optimisation, Sunderland CCG.
- Andrew Lloyd (AL) Consultant Anaesthetist and Chair of South Tees D&T, The James Cook University Hospital (JCUH)
- Simon Thomas (ST) Consultant Physician, Newcastle upon Tyne NHS Foundation Trust
- Matthew Grove (MG) Consultant Rheumatologist, Northumbria Healthcare NHS Foundation Trust.
- Toks Sangowawa (TS) Clinical Advisor/Locum Consultant in Public Health, South Tyneside MBC.

In Attendance: Dr Paul Reading – Consultant Neurologist, JCUH – item 3

Apologies were received in advance from: Tim Donaldson, Ali Wilson, Joe Corrigan

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 interest to be made Andrew Lloyd declared an interest in Pitolisant as the appeal came from clinicians within his Trust. It was agreed he could take part in the discussion and related decision making. It was also noted that the chair had previously met with representatives of Freestyle Libre to discuss the distribution arrangements for the device but this was after NTAG/RMOC had made their recommendation and made no impact on it.

1) Draft Minutes February 2018 Meeting

The group approved the February 2018 minutes.

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

2) Matters Arising

NTAG Membership – discussed under item 10.

3) Appeals: Pitolisant

NTAG agreed at November 2017 meeting that there were grounds for appeal on the NTAG recommendation from June 2017 not recommending the use of Pitolisant on the following basis:

- Additional information had been presented suggesting a pathway for use which was not available previously.
- Costings considered by NTAG may not reflect proposed place in therapy in the North East & Cumbria, and give a true reflection of potential patient numbers.

The appeal was discussed initially at the February 2018 NTAG meeting and further information was requested from the specialists.

Dr Reading presented the case for Pitolisant to the meeting including some patient testimonials on his experience in prescribing the drug over the past 2 years.

The following key points were raised in the presentation and the discussion that followed:

- Nacrolepsy affects 1 in 2000 but only 50% of patients are diagnosed.
- Cateplexy can be the most disabling aspect and affects two thirds of patients with narcolepsy.
- It is rare to normalise a narcoleptic patient and two thirds cannot work as result.
- Approx. one third of patients in clinical practice do not response to modafinil (1st line therapy) +/- dexamefetamine or methylphenidate.
- Sodium oxybate is not a cost-effective treatment option in adults.
- No additional published clinical evidence other than that previously considered is available.
- Trials to date are small but similar in size to other trials in narcolepsy.
- In the real world in his opinion pitolisant is probably more efficacious than modafinil, and helps with cataplexy unlike modafinil. It also has a better side-effect profile than modafinil.
- It was noted that trial data may not capture improvements in quality of life with pitolisant as difficult to include objective and validated measures to do this.
- Difficult to do a cost-effectiveness study as no data on numbers of patients maintaining employment for the different treatment options.
- Usually takes two weeks to know if patient will benefit from pitolisant, and any benefit is sustained. It may also allow for use of stimulants to be decreased.
- Difficult to identify which patients may benefit the most from pitolisant but most keen to use in younger populations and those who cannot manage with daytime naps/other lifestyle changes.
- Unable to explain fully disparity in patient numbers being treated with Pitolisant between the RVI and James Cook but this could be due to personal interest/experience and differences in numbers of patients seen.
- The group were made aware of the commissioning position elsewhere in the UK.

After further discussion NTAG agreed that Pitolisant may offer a further treatment option in carefully defined subset of patients with narcolepsy who may benefit the most from it. In order for this drug to be used in the most cost-effective way NTAG felt that Pitolisant needs to be used in those patients in whom it will make the most difference to their quality of life

NTAG was therefore is minded to approve the use of Pitolisant for third line use but only if it is possible to define in the proposed pathway those patients in whom it may be most beneficial and include some measurement of benefit/outcome.

It was agreed to ask Dr Reading to work with his colleagues in the North East to define a subset of patients in whom Pitolisant will have the most benefit and how this benefit/patient outcome could be measured. The Chair of NTAG would then take Chair's Action to approve an updated pathway and recommendation this basis to prevent further delay.

ACTION:
Secretary to contact specialists to try and draft a recommendation for Chair's Action to define the patient group that will benefit the most from Pitolisant and how this benefit/patient outcome could be measured.

4) Ferric Maltol for Iron Deficiency Anaemia in Inflammatory Bowel Disease – proposed change from secondary care only prescribing

A request has been received from Newcastle-upon-Tyne Hospitals NHS Foundation Trust to review the requirement in the current NTAG recommendation from September 2016 for Ferric Maltol in the management of Iron Deficiency Anaemia in Inflammatory Bowel Disease to be initiated and prescribed by an IBD specialist.

The group discussed that the greatest cost savings compared to IV iron are to be made when ferric maltol is prescribed in primary care and that use does not require any specialist monitoring that could not be carried out in primary care. On this basis the group agreed that was no clinical reason to restrict prescribing to secondary care but that some sort of checklist/information sheet for GPs would useful in helping to control prescribing. It was felt that local APCs would be best placed to produce a local checklist/information sheet for GPs on the prescribing of ferric maltol.

The group agreed to update its current recommendation on the use of Ferric Maltol for Iron Deficiency Anaemia in Inflammatory Bowel Disease to allow GPs to prescribe following a recommendation from an IBD specialist.

ACTION: Secretary to update recommendation as above.

5) Appraisal: Ferric Maltol for Iron Deficiency Anaemia

The appraisal report was introduced by the secretary. A request has been received from Newcastle-upon-Tyne Hospitals NHS Foundation Trust to review the new license extension for Ferric Maltol in the management of iron deficiency anaemia.

The group noted there is no new clinical evidence to support the license extension of ferric maltol. The EMA granted the license extension on the basis that patients with inflammatory bowel disease are the 'worst case' population who are commonly intolerant to oral ferrous products.

The use of ferric maltol as an alternative to IV iron after the failure of oral iron has the potential for some cost savings as costs less than a referral for IV iron in secondary care.

The group agreed to recommend the use of oral Ferric Maltol as an alternative option in adult patients with mild to moderate iron deficiency anaemia who have been unable to tolerate at least two oral ferrous salts due to adverse effects after an adequate trial (e.g. 3 months) and who would otherwise be treated with IV iron. The recommendation to prescribe Ferric Maltol should be made by a secondary care specialist experienced in the management of IDA.

ACTION: Secretary to draft recommendation as above.

6) Appraisal: Lycra Garments for the management of cerebral palsy and other neurological or musculoskeletal conditions – re-review

The appraisal report was introduced by the secretary. The request to review the current NTAG recommendation from February came from the South IFR Panel.

No new studies have been published since the last NTAG recommendation was published and clinicians report no change in practice or prescribing. It is felt that whilst the criteria specified in the NTAG recommendation are only criteria to for consideration not for approval of an IFR request they are leading to high approval rates. It was noted that most requests occur in the north of the region and in the whole of the North East there has been an increase in the number of IFR requests in the last 12 months.

The group agreed not to make any changes to its current recommendation as no new clinical evidence available.

ACTION: Secretary to draft recommendation as above.

7) Apprasial: Transcutaneous vagus nerve stimulation for treatment of cluster headache and migrane – re-review

The appraisal report was introduced by the secretary. The request to review the current NTAG recommendation for transcutaneous vagus nerve stimulation for the reatment of cluster headache and migraine came from Newcastle-Gateshead CCG and Newcastle-upon-Tyne Hospitals NHS Foundation Trust via the chair.

NTAG last reviewed this device in February 2017 and did not approve because the group were concerned about the limited evidence of efficacy and cost effectiveness for both cluster headaches and migraine and it agreed with the NICE Interventional Procedures Guidance that further research is required.

The group discussed the new evidence that is now available and felt it does not change the evidence base significantly. Communication with a specialist in the region indicates that they wish to use for use in the management of cluster headache and do not see a place for this of this device in the management of migraine currently. This is because there is unmet clinical need in the management of cluster of headache.

The group discussed a new economic analysis published since February 2017 and noted that gammaCore may be no more expensive that current therapy and may be very slightly cost-saving.

The group agreed that there is an unmet clinical need in the management of chronic cluster headache and that gammaCore may offer a further treatment option in these patients when verapamil and topiramate have failed, and before trialling lithium and implanted devices such as occipital nerve stimulation or referral for invasive brain stimulation.

The group agreed to recommend the use of non-invasive transcutaneous vagus nerve stimulation (gammaCore) for the treatment of cluster headache as there is an unmet clinical need in the management of chronic cluster headache and that gammaCore may offer a further treatment option in these patients when verapamil and topiramate have failed, and before trialling lithium and implanted devices such as occipital nerve stimulation or referral for invasive brain stimulation.

NTAG continues to not recommend the use of non-invasive transcutaneous vagus nerve stimulation for the treatment of migraine.

ACTION: Secretary to draft recommendation as above.

8) Freestyle Libre – proposed change from secondary care only prescribing

Following the last regional Diabetes Network meeting in June 2018 NTAG have been asked to review their current recommendation on Freestyle Libre to allow continuation of prescribing by GPs once initiated by secondary care. It was felt that before the secondary care only restriction was relaxed that CCGs would wish to see the audit data on outcomes that was a condition of the current RMOC recommendation. It was agreed to make no change to the recommendation at this time as no audit data has yet been published by the ABCD and it was noted that North RMOC committee is to discuss at their next meeting in November 2018.

9) 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.

10) NTAG Membership

a) Secondary Care vacancies

Following the last NTAG meeting the Chief Pharmacists at Gateshead Health NHS Foundation Trust, County Durham & Darlington NHS Foundation Trust and City Hospitals Sunderland have been approached to seek a new provider Trust representative to attend NTAG but no response has been received.

It was also agreed try and seek a further new Secondary Care representative via the North East & Cumbria Chief Pharmacists network.

b) Primary care medicines vacancies

It has been identified that a new Operations representative from CCGs is required following the retirement of the current representative.

The group also discussed the inclusion of Hambleton, Richmondshire and Whitby CCG within the area covered by NTAG now that they are seeking to become membership of regional CCG forum, and the need for named deputies for the current GP representatives to NTAG.

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

ID to seek a named deputy for the current GP representatives to NTAG.

ID to write to Hambleton, Richmondshire and Whitby CCG acknowledging that they are part of NTAG now and would they like to nominate someone to fulfil a deputy role on the NTAG membership.

NB to seek new Operations representative from CCGs to NTAG.

11) Work Plan.

The group discussed the work plan.

It was agreed to add the following to the workplan for the November 2018 meeting:

- Erenumab for migraine prophylaxis – licensed now and expected to be launch in summer 2018. 1st in class and likely to be PBR excluded.
- Actipatch® - now available in Drug Tariff for the management of localised musculoskeletal/chronic pain
- Sufentanil (Duzevo®) – licensed for acute to moderate severe pain.

12) NTAG Annual Report June 2018

NTAG Annual Report for 2017/18 was presented to and approved by the group subject to the Chair completing the Chairman's Foreword.

ACTION:
ID to complete Chairman's Foreword for NTAG Annual Report 2017/18.

GM to send NTAG Annual Report 2017/18 to Northern CCG Joint Committee and publish on website.

13) AOB

Nil

No other business was raised and the meeting concluded.

The date of the next meeting was agreed to be 20th November 2018.

Minutes produced by G Mankin, Professional Secretary to NTAG, 5th September 2018