Northern Treatment Advisory Group

Minutes of meeting held on the 21st November 2017, 9-12am,

Meeting Room 4, The Durham Centre

Present:

- Ian Davidson (ID) Director of Quality and Safety, North Durham CCG & Chair of NTAG.
- Matthew Grove (MG) Consultant Rheumatologist, Northumbria Healthcare NHS Foundation Trust.
- Gavin Mankin (PGM) Principal Pharmacist – Medicines Management, RDTC (professional secretary)
- Ali Wilson (AW) Chief Officer, Darlington CCG and Hartlepool & Stockton-on-Tees 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
- Nick Timlin (NT) General Medical Practitioner, Hartlepool & Stockton-on-Tees CCG.
- Hannah Willoughby (HW) Medicines Optimisation Pharmacist, Sunderland CCG.
- Jill McGrath (JM) Head of Finance, Newcastle Gateshead CCG.
- Andrea Loudon (ALo) Primary Care Development and Medicines Lead, North Cumbria CCG.

In Attendance: Nil

Apologies were received in advance from: Janette Stephenson, Joe Corrigan, and Tim Donaldson.

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 under this agenda item but not in a related decision making.

1) Draft Minutes September 2017 Meeting

The group approved the September 2017 minutes.

ACTION: Secretary to publish September 2017 minutes on the NTAG website.

2) Matters Arising

a) Bezlotoxumab for the treatment of C.difficile

The group agreed at its September 2017 meeting that this may be of some value to those patients who are at risk of recurrent infection and they were minded to approve use in severe cases however they wanted further information from specialists around where they would see this drug fitting in the treatment pathway. As yet no feedback from specialists has been received. It was agreed that further feedback would continue to be sought and this would be discussed again at the meeting in February 2018.

ACTION: Secretary to contact specialists for feedback

3) Appraisal: Intravitreal Bevacizumab for the treatment of CRVO and NVG

The group agreed to defer the review of the existing NTAG guidance from 2011 in light of the potential legal challenges to the new North East and Cumbria regional policy regarding the treatment of Age-related Wet Macular Degeneration, based upon the prescribing of bevacizumab (Avastin®) as the first-line treatment option for patients newly diagnosed with wAMD.

4) Appraisal: Dupilumab for atopic dermatitis

The appraisal report was introduced by the secretary. This had been added to the work plan via horizon scanning. There had been no specific requests for it by specialists, however it is likely to be PbR excluded and therefore commissioned by CCGs so was felt to be useful for NTAG to consider.

Dupilumab (Dupixent®▼) is a fully human monoclonal antibody that inhibits interleukin-4 and interleukin-13 signalling. It is the first targeted biologic therapy approved for use in AD, and is licensed for the treatment of moderate-to-severe AD in adult patients who are candidates for systemic therapy.

The efficacy of dupilumab was evaluated in three pivotal randomised, double-blind, placebo-controlled studies, consisting of two identical 16-week monotherapy studies (SOLO 1 and SOLO 2), and a 52-week study of dupilumab with concomitant use of topical corticosteroids (CHRONOS). The studies enrolled a total of 2,119 subjects 18 years of age and older with moderate to severe AD not adequately controlled by topical medication. In all three studies both dupilumab dose regimens (300 mg Q2W and QW) were superior to placebo for the co-primary endpoints of IGA 0 or 1 response, and EASI 75. Similar results were found for all secondary endpoints including improved patient reported symptoms and health-related quality of life. In all the studies, the once weekly dupilumab regimen did not demonstrate any additional benefit over the once fortnightly dupilumab regimen (approved dose). There are no head-to-head trials comparing dupilumab with other systemic therapies.

The rates of treatment-emergent adverse events (TEAEs) were similar across dupilumab-exposed and placebo-exposed groups in both the monotherapy and concomitant TCS safety pools. The most frequently reported adverse reactions include injection site reactions, conjunctivitis, blepharitis and oral herpes. The rates of serious TEAEs were slightly higher in the placebo groups in both pools. A higher incidence of eye-disorders was observed in the dupilumab groups compared to placebo. Although the majority of these were mild to moderate in severity and responded to treatment with topical preparations a significant proportion had not resolved during the study period.

Dupilumab It is not expected to be marketed in the UK until Q2 2018 and the NHS cost is not yet known. In the US, dupilumab currently costs $37,000 per patient per year. In the UK, it is estimated there are 14 adults per 100,000 population with moderate AD, and 6 with severe AD who may be eligible for treatment with dupilumab. If it is assumed that 50% of the patients with severe AD are treated at a cost of £15,000 per year this would represent an estimated cost pressure of £45,000 per 100,000 population, which would equate to around £1.08 million for the NTAG area.

The group agreed that it was unable to make a recommendation on Dupilumab at this stage because:

- **No UK price currently available**
- **No views of regional dermatologists have been sought as to its place in therapy.**

ACTION: Secretary to contact specialists for feedback.

5) Appeals: Pitolisant

This item was introduced by the secretary.

The group discussed a letter that had been sent to NTAG from Dr Adrienn Petreczky Consultant Neurologist, South Tees NHS Foundation Trust. The group had been asked to re-consider their recommendation on pitolisant and a potential place in therapy had been identified by the author.

The group agreed there were grounds for appeal 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 group agreed to seek further information from the specialists at James Cook and the RVI, and seek a regional consensus on the use of pitolisant to come back to the February 2018 NTAG meeting for the appeal to be discussed in full.

ACTION:
Secretary to contact specialists at RVI and James Cook to confirm both centres agree on the suggested pathway/place in therapy presented with the appeal.

Secretary to confirm costings and potential patient numbers with specialists.

Secretary to check commissioning status of pitolisant elsewhere in UK.

6) Regional Medicines Optimisation Committee

a) RMOC Recommendations – NTAG Processes

The group discussed how RMOC Recommendations are adopted within the North East & Cumbria as currently there is no regional agreement on how RMOC Recommendations are enacted by CCGs.
It was agreed that NTAG should not re-debate RMOC decisions and that a paper should go to the December 2017 Regional CCG Forum to decide how the NE&C region handles RMOC Recommendations.

ACTION:
Chair/JS to draft paper to go to the December 2017 Regional CCG Forum to decide how the NE&C region handles RMOC Recommendations.

b) Freestyle Libre Statement

The group dicussed and endorsed the Regional Medicines Optimisation Committee (RMOC) position statement on the NHS prescribing of Freestyle Libre® Flash Glucose Monitoring System of the 1st November 2017.
NTAG recommends Freestyle Libre® as an option for glucose monitoring in Type 1 diabetic patients only in the North East and Cumbria for patients who fulfil the RMOC criteria for the device
The device should not be prescribed in primary care and should only be initiated and prescribed by diabetic specialists. This is because until further trial data is available, it is recommended that audit data on the use of Freestyle Libre® is collected through its use in limited and controlled settings where patients are attending for Type 1 diabetes care, secondary care is best placed initially to collect the necessary audit data.
The requirement to only be prescribed in secondary care would mean secondary care costs would increase and some arrangement to cover costs from the primary care budget would have to be made with commissioners/contracting/finance/Trusts, but this was felt not be an insurmountable barrier to implementation.
The group noted that current self-funders must fulfil at least one of the RMOC initiation criteria for the device to be prescribed on the NHS.
The group also discussed correspondence received from the NE&C Regional Children and Young People's Diabetes Network regarding the use of Freestyle Libre® in children and young people. NTAG agreed it was important to have a consistent national and regional position on the use of Freestyle Libre® to avoid postcode prescribing, and therefore agreed to endorse the nationally agreed position produced via the Regional Medicines Optimisation Committee (North). If there are additional criteria/indications for use in paediatrics that the North East and Cumbria Children and Young People's Diabetes Network feel should also be approved then NTAG agreed these should be referred to the Regional Medicines Optimisation Committee for consideration to ensure a consistent national and regional position is adopted. It was also agreed to stick with current Flash Glucose Monitoring System nomenclature for describing the system to maintain consistency with how the device is described by NICE, RMOC and the manufacturer.

ACTION: Secretary to draft statement for Chair's approval to go on NTAG website ASAP endorsing the RMOC position statement on NHS prescribing of Freestyle Libre® Flash Glucose Monitoring System with the NE&C.

7) Work Plan.

The group discussed the work plan. It was agreed to remove the following from the workplan:

- Brodalumab as NICE TA is due in May 2018.
- Sirukumab as licensing application withdrawn by manufacturer.
- Adalimumab biosimilars as RMOCs and NHS England leading on the introduction of biosimilars.

8) AOB

Dates for 2018
The meeting dates for 2018 were circulated to the group for information.

No other business was raised and the meeting concluded.

The date of the next meeting was noted to be 27th February 2018.

Minutes produced by G Mankin, Professional Secretary to NTAG, 23rd November 2017