Northern Treatment Advisory Group

Minutes of meeting held on the 3rd September 2019, 9-12am,

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.
- Claire Sands (CS) Assistant Head of Finance, Newcastle Gateshead CCG.
- Siobhan Brown (SB), Chief Operating Officer, Northumberland 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)
- Matthew Lowery (ML) Formulary Pharmacist, Newcastle upon Tyne NHS Foundation Trust

In Attendance: Nancy Kane, Senior Medical Information Scientist, RDTC

Apologies were received in advance from: Tim Donaldson, Simon Thomas, Joe Corrigan, Ian Morris, and Andrea Loudon

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 none were declared.

1) Draft Minutes June 2019 Meeting

The group approved the June 2019 minutes.

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

2) Matters Arising

Impact on Primary Care Prescribing Data of NTAG Recommendations from 2017 to 2018 – data has been shared with CCG Medicines Optimisation Teams.

Impact on Secondary Care Prescribing Data of NTAG Recommendations from 2017 to 2018 – data still to be requested from Secondary Care Pharmacy Teams in North East & North Cumbria.

3) Appraisal: Liposuction for Lipoedema and Lymphoedema

The 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 further information on the following for the next NTAG meeting before a final recommendation could be made:

- Evidence for using German technique rather than Bronson technique plus any comparision between the two in terms of both clinical and cost-effectiveness.
- Can the specialists tighten the proposed criteria for use?
- Any information and costs available for other UK providers other than Dundee?
- How do patients that have been approved via IFR fit the proposed criteria, and what has been their outcome clinically?

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

4) Appraisal: Andexanet alfa – antidote to oral factor Xa inhibitors

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 tariff excluded and therefore commissioned by CCGs so was felt to be useful for NTAG to consider prior to NICE TA being available in March 2020 not that the product is available.

Andexanet alfa is a first-in class Factor Xa inhibitor antidote licensed in the EU for use in adult patients treated with a direct Factor Xa inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

Patients taking Factor Xa inhibitors who need immediate reversal due to severe or life-threatening bleeding are currently managed using prothrombin complex concentrates (unlicensed indication), fresh frozen plasma and anti-fibrinolytic agents.

The group was concerned about the following:

- The lack of randomisation or comparison with a control group other than placebo in the ANNEXA-4 trial. There is therefore no clear evidence whether it is more effective in achieving haemostasis than conventional care alone.
- Overall, the evidence is limited and no comparative studies are available to determine whether 4-PCC or aPCC would still constitute a comparable effective alternative to andexanet alfa in the management of direct FXa-related major bleeding.
- Unlike idarucizumab (Praxbind®▼), it is not licensed when rapid reversal of anticoagulant effects is required for emergency surgery/urgent procedures
- Poor or no efficacy was observed in 18% of patients treated despite a reduction in anti-FXa activity
- Further information on potential patient numbers who may require andexanet alfa is required so that cost-effectiveness versus current treatment options can be accurately assessed.

- Concerns around cost-effectiveness versus current treatment options based on the current evidence, and the current NHS List price. It is not yet known whether any commercial arrangements will be offered.
- Need better idea of likely potential patient numbers and criteria for when use of this agent might be considered over other treatment options from regional haematologists.

Two dose regimens of andexanet alfa are approved: a low and a high dose regimen, requiring 5 or 9 vials respectively. The listed NHS price for 4 vials of Ondexxya® 200 mg powder for solution for infusion is £11,100, exclusive of VAT. Prices for low and high dose will therefore be £13,875 and £24,975 per patient per dose, respectively

The group noted that NICE is due to issue a technology appraisal for andexanet alfa in March 2020.

After discussion the group agreed not to currently recommend the use of andexanet alfa (Ondexxya®) for use in adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

ACTION: Secretary to draft recommendation as above.

5) Appraisal: Patiromer for hyperkalaemia

The appraisal report was introduced by the secretary. This had been added to the work plan at the request of the North of Tyne, Gateshead and North Cumbria Area Prescribing Committee as the NICE TA has been delayed until February 2020 and they feel a regional position would useful until then.

Patiromer is a treatment option for people with high blood serum potassium levels (hyperkalaemia). The company proposes that it would benefit people with stage 3 and 4 chronic kidney disease who are having a renin-angiotensin-aldosterone system inhibitor and who have high levels of serum potassium.

The group reviewed the evidence as per the current SMC recommendation and the NICE Apprasial Consultation Document (Oct 2018)

The NHS List Price is £300 per 30-sachet pack, each sachet contains 8.4g or 16.8g of patiromer. It is not yet known whether any commercial arrangements will be offered.

The group was concerned about the following:

- The NICE Apprasial Consultation Document (Oct 2018) states that patiromer is not recommended for treating hyperkalaemia in adults.
- There was not an active treatment control group in the clinical studies.
- NICE and the SMC both state that the results of clinical trials with patiromer may not be relevant to NHS clinical practice because in the trials most people had a lower level of potassium than would be treated in the NHS.
- Some groups of patients were excluded from the OPAL-HK study, who may be required a renin-angiotension-adosterone system inhibitor (e.g. patients with recent cardiovascular

events, and severe heart failure). This may reduce the generalisability of the study results to real-life practice.

- There is also no evidence to show that patiromer extends life or improves quality of life compared with standard care in people who would have treatment for hyperkalaemia in the NHS.
- In the trial twice daily dosing was used but patiromer was licensed for once daily dosing to allow for a three hour window before taking other concomitant medicines to migate the effects of drug interactions/binding.
- Limited evidence in severe hyperkalaemia and in patients with end-stage renal disease receiving dialysis.
- The current evidence relates to acute use. In the OPAL-HK patients received up to 12 weeks treatment with patiromer. Other studies were up to 1 year duration. Longer-term is needed as partiromer would most likely be used as part of the patient's chronic disease management.
- Concerns around cost-effectiveness versus current treatment options based on the current evidence, and the current NHS List price. It is not yet known what level of any discount or any commercial arrangements may be offered by the manufacturer.

After discussion it was agreed that does not recommend the use of patiromer (as patiromer sorbitex calcium) for the treatment of hyperkalaemia in adults.

ACTION: Secretary to draft recommendation as above.

6) Regional Medicines Optimisation Committee

- **RMOC Newsletter 2019 – issue 5**
- **RMOC Newsletter 2019 – issue 6**

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.

7) 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.

b) Primary care medicines vacancies

Following the last NTAG meeting those stakeholder CCGs which are not currently represented at NTAG have been contacted to seek a named deputy for the current GP representatives to NTAG but no response has been received as yet. The professional secretary will follow this up prior to the next NTAG meeting.

c) Patient/Lay representation

Following the last NTAG meeting a potential new Patient/Lay representative to NTAG has been identified following an approach to County Durham Healthwatch. The professional secretary is to meet with them to discuss their potential involvement and assess their suitability.

8) Work Plan.

The group discussed the work plan.

- Buprenorphine long acting injection (Buvidal®) – has been been referred to RMOC South and so advised to wait to see what further guidance is issued nationally by them plus timescales for this.
- Pitolisant for Narcolepsy – it was noted that then when this was approved by NTAG in Nov 2018 that prospective data will 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 will also monitor adherence to prescription guidelines. This audit data will be requested for the February 2019 NTAG meeting.

No other suitable topics have currently been identified for addition to the workplan.

9) Review of NTAG Recommendation – Doxylamine/Pyridoxine (Xoneva®) for Nausea & Vomiting in Pregnancy in light of published NICE and SMC reviews

NTAG reviewed its current recommendation from Feb 2019 regarding Doxylamine/Pyridoxine (Xoneva®) as a NICE Evidence Summary and a review by the SMC have both now been published.

NTAG agreed that no change to its current recommendation was needed as RCOG guidelines have not been updated yet, and a full NICE TA had not been issued. It also noted that the SMC decision supported the current NTAG position not to recommend.

This NTAG recommendation will be reviewed in light of publication of updated clinical guidelines from the Royal College of Obstetricians and Gynaecologists.

10) AOB

Nil

No other business was raised and the meeting concluded.

It was agreed to cancel November 2019 meeting at this stage due to lack of agenda items. If need arises an extra meeting may be held virtually to discuss any urgent items of business.

The date of the next meeting was agreed to be 25th February 2020

Minutes produced by G Mankin, Professional Secretary to NTAG, 4th September 2019