# Minutes of meeting held on the 27th February 2018, 9-12am,

# Board Room, The Durham Centre

**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)
- Matthew Grove (MG) Consultant Rheumatologist, Northumbria Healthcare NHS Foundation Trust.
- Nic Bailey (NB) Chief Officer, North Durham CCG & DDES CCG
- Nick Timlin (NT) General Medical Practitioner, Hartlepool & Stockton-on-Tees CCG.
- Elizabeth Mallett (EM) Medicines Optimisation Pharmacist, Sunderland CCG.
- Claire Sands (CS) Assistant Head of Finance, Newcastle Gateshead CCG.
- Janette Stephenson (JS) Head of Medicines Optimisation, North East Commissioning Support Unit.
- Matthew Lowery (ML) Formulary Pharmacist, Newcastle upon Tyne NHS Foundation Trust

In Attendance: Nil

Apologies were received in advance from: Tim Donaldson, Andrea Loudon, Ali Wilson, Simon Thomas, Andrew Lloyd, Hannah Willoughby, Joe Corrigan.

The group noted that as apologies from one of the provider representatives had been received the meeting would not be quorate however GM stated that he would run all decisions by the full membership prior to issuing them.

The group noted that Public Health was struggling to attend meetings but as per the terms of reference their views were sought via email prior to the meeting.

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 it was declared that the chair had recently 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 November 2017 Meeting

The group approved the November 2017 minutes.

**ACTION: Secretary to publish November 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.

The group noted that Bezlotoxumab is on the workplan of NICE for a TA but no firm date for publication is currently available. This drug had been added to the NTAG workplan via horizon scanning as high cost CCG commissioned excluded drug. To date there have been no specific requests for it from specialists.

Feedback has now been received from specialists at North Cumbria University Hospitals, South Tees Hospitals NHS Foundation Trust, Newcastle upon Tyne Hospitals NHS Foundation Trust, Northumbria Healthcare and Gateshead Health NHS Foundation Trust. All Trusts contacted felt it would be appropriate to wait for guidance from PHE or the NICE TA as place in therapy will inevitably be guided nationally by NICE and/or PHE. This was also the view of public health.

**The group agreed to not to issue a recommendation until further guidance from NICE/PHE on place in therapy available as no appetite from specialists to use at this stage.**

**ACTION: Secretary to remove from current workplan but bring back to group if and when NICE/PHE issue guidance on use.**

**b) Dupilumab for atopic dermatitis**

The group agreed at its November 2017 meeting on the clinical evidence for Dupilumab but it was unable to make a recommendation on Dupilumab at that stage because no UK price was available and it wanted to seek the views of regional dermatologists as to its place in therapy.

This had been added to the work plan via horizon scanning. To date there have 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. The product has been referred to NICE for a TA with an estimated publication of August 2018.

Dupilumab was launched in the UK in December 2017 and it currently available to some Trusts via an early access scheme until the NICE TA is available. The NHS list price currently is £1264.89 ex VAT for 2 x 300mg/2ml pre-filled syringes this equates to £1265 per patient per month ex VAT for the usual maintenance dose.

Feedback has now been received from dermatologists at South Tees Hospitals NHS Foundation Trust, Newcastle upon Tyne Hospitals NHS Foundation Trust, and County Durham & Darlington NHS Foundation Trust. All the Trusts confirmed they were not participating in the early access scheme and would be guided by NICE as to where Dupilumab fits in the treatment pathway in relation to other systemic therapies for atopic dermatitis. All the Trusts indicated that they would want to have access to the drug once it receives NICE approval. Public Health was of the view that it was appropriate to wait for the NICE TA to be published.

**The group agreed to not to issue a recommendation on Dupilumab for atopic dermatitis as a NICE TA was in progress and regional dermatologists have indicated they wish to wait for this NICE TA to be published to guide them on how it should be used.**

### c) RMOC recommendations – NTAG processes

A paper was taken to the December 2017 Regional CCG Forum to decide how the NE&C region handles RMOC Recommendations and Outputs.

The CNE CCG forum agreed that the route for consideration of RMOC recommendations should be NTAG (formulary) and CNE MO forum (QIPP advice & guidance)

### d) Freestyle Libre

The Freestyle Libre – Implementing NTAG Recommendations statement from NECS dated 8.1.2018 was circulated to the group for information.

## 4) Appraisal: PDE5-Inhibitors in post-radical prostatectomy

The appraisal report was introduced by the secretary together with an UKMi Q&A entitled "What is the rationale and evidence for the use of phosphodiesterase-5 inhibitors as supportive therapy to rehabilitate erectile function after nerve sparing radical prostatectomy?'. This had been added to the work plan at the request of ND &DDES CCGs and the NTAG Chair. It is high volume prescribing and medicines management teams are asking for evidence in favour of daily dosing with either tadalafil or sildenafil in patients pre or post radical prostatectomy as many GPs are being asked to prescribe this regimen by their urologist and/or oncologist.

Erectile dysfunction (ED) is extremely common following treatment for prostate cancer, since the available treatments (radical prostatectomy, androgen deprivation therapy, radiotherapy) can cause physical trauma, vascular changes and endocrine changes, all of which can have a negative impact on erectile function.

Standard management for ED involves prescription of PDE5 inhibitors such as sildenafil or tadalafil. These treatments are effective in men with ED due to treatment for prostate cancer, but there is some debate as to the most appropriate treatment regimen. UK clinical practice guidelines recommend either once daily or on-demand PDE5 inhibitors, or some combination of the two. There is limited evidence comparing daily and on-demand treatment regimens. There was no published clinical evidence of any difference in outcomes between daily and on-demand use of any PDE5 inhibitor, and there was no evidence found comparing sildenafil with tadalafil.

The group noted that daily use of PDE5 inhibitors is more expensive than on-demand use. Sildenafil is currently less costly than tadalafil. However, tadalafil came off patent relatively recently and the Drug Tariff price may change in coming months.

**The group agreed that on the basis of evidence available there was no evidence to recommend the use of daily dosing over on-demand dosing of PDE5 inhibitors, and there was no evidence that tadalafil was superior to sildenafil. On this basis NTAG agreed that there may be a case for on-demand dosing using the PDE5 inhibitor with the lowest acquisition cost, currently this is generic sildenafil.**

| **ACTION: Secretary to draft recommendation above.** |
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## 5) 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 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. This information has now been received and was presented to the committee by the secretary.

Both the RVI and James Cook clinicians are in agreement with the pathway proposed by James Cook in their appeal letter but the committee questioned the disparity in patient numbers being treated with Pitolisant between the RVI and James Cook and wanted to understand the reason for this difference before making a final decision on the appeal.

The group noted that prior to the NTAG recommendation of June 2017 both the North of Tyne & Gateshead APC (April 2016) and the South Tees Hospitals NHS Foundation Trust D&T (July 2015) had approved the addition of Pitolisant to their respective formularies as a RED drug for use in patients with narcolepsy who experience psychomotor side effects with modafinil and dexamfetamine. Primary care prescribing data for the NTAG region suggests the RED drug status is being adhered to across the region and all prescribing with few exceptions is currently being retained within secondary care.

Following the November 2017 meeting a revised cost model has been produced which more accurately reflects current patient numbers and costs in the NTAG region. This was presented to and accepted by the group though concerns were expressed about the potential for prescribing costs to be passed on to primary care in the future. The original NTAG cost analysis appears to have over-estimated the potential cost impact in the NE&C since it did not account for patients discontinuing treatment after an initial trial or the split in patient numbers between the two different maintenance doses. Pitolisant is not a tariff excluded drug or NHSE commissioned drug.

In practice communication with the specialists suggests at least 50% of patients who are resistant/intolerant of standard wake-promoting therapy and who are trialled on Pitolisant remain on it and only the 18mg or 36mg doses are used for maintenance therapy at both the RVI and James Cook. A trial of 4 weeks is usually enough to decide efficacy. With approx. 50% of patient who remain on it following a 4 week trial requiring the higher dose of 36mg OD.

**ACTION:**
**Secretary to contact specialists at RVI and James Cook to understand disparity in patient numbers between the RVI and James Cook who have been prescribed pitolisant to date.**

## 6) 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.

## 7) NTAG Membership

The group reviewed the current NTAG membership and noted the current vacancy in provider representation for a District General Hospital, and that a number of the positions do not have a formal deputy identified.

It was agreed to approach Gateshead Health NHS Foundation Trust, County Durham & Darlington NHS Foundation Trust and City Hospitals Sunderland to seek a new provider Trust representative to attend NTAG. It was also agreed to identify a named deputy for the current GP representatives.

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.

**ACTION:**
**Secretary to contact Gateshead Health NHS Foundation Trust, County Durham & Darlington NHS Foundation Trust and City Hospitals Sunderland 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.**

## 8) Work Plan.

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

- Bezlotoxumab as on NICE TA workplan and await guidance from PHE
- Dupilumab for atopic dermatitis as NICE TA us due in Aug 2018 and specialists indicated happy to wait for NICE guidance.

It was agreed to add the following to the workplan:

- Erenumab for migraine prophylaxis – not yet licensed but expected to be launch in summer 2018. 1st in class and likely to be PBR excluded.
- Cariprazine for schizophrenia – suggested by TEWV Mental Health Trust. Licensed in UK but not yet launched. Agreed with mental health post-meeting not to include in the NTAG workplan at this stage.

Public Health and APC Professional Secretaries in NTAG region had been contacted for suggestions of items requiring NTAG review but to date none have been identified or submitted.

<u>Novel oromucosal fentanyl preparations</u>

A suggestion from South Tees NHS Foundation Trust that NTAG re-review is recommendation on novel oromucosal fentanyl preparations from July 2011 was discussed by the group. This request

as arisen from the recent NHS England work on 'Items Which Should Not Routinely be Prescribed in Primary Care' which included the following recommendation for CCGS:

- *Advise CCGs that prescribers in primary care should not initiate immediate release fentanyl for any new patient.*
- *Advise CCGs to support prescribers in deprescribing immediate release fentanyl in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.*
- *Advise CCGs that if, in exceptional circumstances, there is a clinical need for immediate release fentanyl to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.*

*These recommendations do not apply to patients undergoing palliative care treatment and where the recommendation to use immediate release fentanyl in line with NICE guidance (see below), has been made by a multi-disciplinary team and/or other healthcare professional with a recognised specialism in palliative care.*

*NICE CG140 Opioids in Palliative Care states Do not offer fast-acting fentanyl as first-line rescue medication.*

*Due to the recommendations from NICE and immediate release fentanyl being only licensed for use in cancer, the joint clinical working group considered immediate release fentanyl was suitable for inclusion in this guidance with specific exceptions for people receiving palliative care reflecting NICE and the terms of the product licence.*

There is also a review available from PrescQIPP (April 2016) on Immediate Release Fentanyl which suggests that patients receiving the most costly immediate release fentanyl preparations (e.g. Actiq®) who cannot be switched to immediate release morphine could be considered for a switch to a less costly immediate release fentanyl product (e.g. Abstral®).

The group noted that implementation of the previous NTAG recommendation on novel oromucosal fentanyl preparations appears to be good with continued overall low levels of prescribing across all NHS organisations within the North East.

After discussion NTAG agreed not re-review its previous recommendation on novel oromucosal fentanyl preparations as the NTAG recommendation specifically looked at breakthrough cancer pain. The recent NHSE guidance 'Items Which Should Not Routinely be Prescribed in Primary Care' includes the specific exception of people receiving palliative care reflecting NICE guidance and the terms of the product licence. It was felt the choice of novel oromucosal fentanyl preparations was more of local formulary issue and that palliative care should be encouraged to use the preparation of lowest acquisition cost.

## 9) AOB

Nil

No other business was raised and the meeting concluded.

It was agreed to cancel June meeting at this stage due to lack of agenda items. If need arises an extra meeting may be required or held virtually to discuss the further feedback received from clinicians around pitolisant.

The date of the next meeting was agreed to be 4th September 2018.

*Minutes produced by G Mankin, Professional Secretary to NTAG, 28th February 2018*