Northern Treatment Advisory Group

Minutes of meeting held on the 2nd June 2020, 9-11.30am

Virtual Online Meeting via StarLeaf

Present:

- Ian Davidson (ID) Medical Director, County 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, Tees Valley 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.
- Matthew Lowery (ML) Formulary Pharmacist, Newcastle upon Tyne NHS Foundation Trust.
- Robert Lapham (RL) Formulary Pharmacist, South Tyneside & Sunderland NHS Foundation Trust.
- 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
- Andrea Loudon (ALo) Primary Care Development and Medicines Lead, North Cumbria CCG.
- Jim Welch (JW) Patient/Lay Representative.

In Attendance: Nil

Apologies were received from: 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 Jim Welch declared the following:

- Agenda item 3 – JW is registered blind and chair of local blind support group – it was agreed that did not stop him participating in the discussion on this item as he does not have the condition for which verteporfin is used, and does not advise patients/clinician directly on treatment choices.

Robert Lapham, South Tyneside & Sunderland NHS Foundation Trust was welcomed as a new additional secondary care representative to NTAG.

1) Draft Minutes February 2020 Meeting

The group approved the February 2020 minutes.

ACTION: Secretary to publish February 2020 minutes on the NTAG website.

2) Matters Arising

- Review of NTAG recommendation on Sodium oxybate (Xyrem®) in the management of narcolepsy with cataplexy in adult patients in light of RMOC position statement - awaiting RMOC statement on Pitolisant before progressing as may change place in therapy and costings now generic Sodium oxybate available.
- Liraglutide for obesity – NICE TA due March 2020 – to archive NTAG recommendation once NICE TA available. NICE TA delayed due to Covid-19 – 1st appraisal did not recommend use.
- Patiromer for hyperkalaemia – NICE due Feb 2020 - previous NTAG recommendation now archived.
- Liposuction for Lipoedema and Lymphoedema - RDTC unable to progress with specialists due Covid-19.

3) Appraisal: Verteporfin photodynamic therapy for chronic central serous chorioretinopathy (updated)

The updated appraisal report was introduced by the secretary. This had been added to the work plan at the request of the Rajen Gupta - Consultant Ophthalmologist RVI.

The reasons for requesting a review of the current NTAG recommendation from November 2014 are that:

- Think we are now outliers in the country as the treatment is being used routinely for this condition.
- Recent Royal College of Ophthalmology seminar discussed its use and presented data on its use.
- No other mechanism for treating these patients other than observation or very rarely focal argon laser. Several patients have lost sight as there is no other available treatment.

NTAG reviewed the new literature published on the use of Verteporfin for chronic CSCR since November 2014. The new published studies do offer a reasonable proxy population in terms of demographics to the population which would receive treatment under this proposal; most patients are male and roughly middle-aged. The duration of symptoms varies between trials; the baseline before treatment reducing to less than 6 months (previous reviews have seen treatment starting at 6 months or greater). The overall impact on acuity across all studies is positive. Since the baseline level of acuity is widely variable, it is unsurprising that the change in acuity is also widely variable. There are also few studies with long-term follow-up, which is an important omission given that recurrence is a well-described part of the natural history of the disease in many cases. Indeed, recurrence and re-treatment is described in a number of the included studies. No new or unexpected safety concerns arose in studies of Verteporfin in CSCR since November 2014.

NTAG noted there is still no NICE guidance on the use of Verteporfin PDT for chronic CSCR, and neither do the Royal College of Ophthalmologists have any formal guidelines on its use.

After discussion NTAG agreed to recommend Verteporfin (Visudyne®) with photo-dynamic therapy (PDT) outside of its product license for the treatment of chronic CSCR for patients that fulfil the following criteria suggested by the specialists:

1. **Non resolving or recurrent CSCR**
2. **Minimum 6/12 duration to rule out spontaneous regression in first eye**
3. **Minimum duration of 4/12 if second eye involvement (i.e. try to treat earlier to preserve structural components and vision)**

4. **Maximum of 2 treatments (if no benefit unlikely to respond to additional treatments)**
5. **Patients to have FFA/ ICG confirmation of diagnosis plus OCT/ OCTA**
6. **Baseline vision at time of treatment and subsequently at 12 months to allow for effect monitoring**

The group considered that the new evidence published since NTAG last reviewed this treatment in November 2014 was sufficient to demonstrate evidence of improved vision acuity and quality of life in a condition where a small improvement can make a significant difference to patients, and where there a limited or no other treatment options. It is also a relatively inexpensive treatment for a small number of patients.

ACTION: Secretary to draft recommendation as above.

4) Appraisal: Infliximab subcutaneous

This had been added to the work plan pre-Covid-19 at the request of RVI, and CCG Medicines Management Leads as felt a regional position would be useful, particularly as different licensed indications to intravenous formulation and potential cost implications.

The product was launched in the UK in March 2020 and it was quickly identified that guidance was needed as part of strategies to manage capacity in hospital day case units and also homecare capacity during the Covid-19 pandemic. As a result an RDTC Covid-19 QAA on Infliximab subcutaneous was produced which was endorsed by NTAG via Chairs Action. This was presented to the NTAG meeting by the secretary. NTAG noted the following key points:

- Infliximab subcutaneous (Remsima SC®) is currently only licensed for Rheumatoid arthritis (RA), and a license extension for IBD is expected in approximately July 2020.
- If localities are considering a managed therapeutic switch programme from Infliximab IV to Infliximab SC this should be done in agreement with Trusts and Commissioners, coordinated via regional procurement to ensure consistency across regions, and to support national constraints around homecare capacity at this time.
- Commissioners should be fully involved in discussions to move to this temporary arrangement, and providers and patients should be aware that post COVID-19 pandemic this service provision may be revised.
- No separate NICE appraisal other than that done for IV formulation expected.
- NICE Evidence Summary in progress – no date when this will be available.
- The introduction of a subcutaneous version of Infliximab is unlikely to dramatically change the initial choice of anti-TNF.
- It is unlikely to produce significant savings to local budgets but will give patients an additional option of a product that can be self-administered and could help reduce local capacity issues.
- There is no data available on switching from a different brand of intravenous Infliximab other than Remsima® to Remsima SC®.
- There are currently constraints around homecare capacity nationally, so the preferred supply route at this time is through hospital pharmacy departments dispensing on an outpatient basis. If supplied via the hospital pharmacy, ancillaries and sharps bins should be supplied where required.

NTAG discussed and agreed to issue a more formal recommendation on the use of Infliximab subcutaneous (Remsima®). Clinicians present with experience in the use of infliximab explained

the Infliximab IV is used as 4th or 5th line treatment option in RA with low numbers of RA patients on it. The IV formulation has a wider license than the Remsima SC® formulation, including use in ankylosing spondylitis, psoriatic arthritis, and psoriasis. In practice some hospital Trusts in the North East reported that they were also currently using the Remsima SC® formulation off-label for the same indications they would use the IV formulation as it is essentially the same active drug. They are doing this as part of their management strategy to reduce hospital day case admissions, and keep immunosuppressed people out of hospital during the COVID-19 pandemic.

Information of the costs of Remsima SC® compared to other biologics and the IV formulation was presented to NTAG.

After discussion NTAG agreed to recommend that Remsima SC® be available as additional treatment option during the Covid-19 pandemic for both licensed and off-label uses as part individual hospital Trust management strategies to reduce hospital day case admissions, and keep immunosuppressed people out of hospital during the COVID-19 pandemic. Remsima SC® could be considered as an option where the patient would otherwise get the intravenous Remsima® formulation of Infliximab. This recommendation is subject to any off-label use of Remsima SC® being considered and approved via individual hospital trust governance processes (including clinical governance) for the use of unlicensed/off-label drugs. It was also agreed that this recommendation would be reviewed after 12 months.

ACTION: Secretary to draft recommendation as above.

5) Appraisal: Inhaled Levodopa for Parkinson's disease

The appraisal report was introduced by the secretary. This had been added to the work plan via horizon scanning as it is not include in the NICE Technology Appraisal work plan. There have been no specific requests for it from specialists.

Inhaled levodopa (Inbrija®) was licensed in September 2019 as alternative to Apomorphine injections for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease. There is currently no UK price or UK SPC, and the manufacturer are still looking for partner to market the product in Europe.

It was agreed to keep this on the work plan and bring back to future NTAG meeting with to seek views of local clinicians when the product is launched in the UK.

6) Appraisal: Vaginal Devices for Female Urinary Stress Incontinence

The appraisal report was introduced by the secretary. This had been added to the work plan at the request of Newcastle Gateshead CCG as felt a regional position would be useful as not all APC's will consider devices even though they can be prescribed on FP10 prescription in primary care.

Diveen®, Contiform® and Efemia® are intravaginal devices usually similar to tampon in shape and size included in the Drug Tariff which are indicated for stress or mixed urinary incontinence. There are other similar devices which are not yet included in the Drug Tariff.

Devices for stress urinary incontinence are not recommended by NICE in NG123 except for occasional use, for example during exercise. It was also noted that they are included in the current PrescQIPP DROP List.

Adverse effects including urinary tract infections, metrorrhagia and residual urine have been reported.

After discussion NTAG agreed not to recommend use of these devices on the NHS because there is a lack of quality evidence currently to support the efficacy of these devices and their use is not currently recommended in NICE guidelines. Should patients wish to use the device it can be purchased over the counter for occasional use, for example during exercise.

ACTION: Secretary to draft recommendation as above

7) Appraisal: Purewick® Female External Urinary Catheter

The appraisal report was introduced by the secretary. This had been added to the work plan at the request of Newcastle Gateshead CCG. It was felt that even if there is little evidence a statement by NTAG to say there is insufficient evidence to recommend use would be very helpful to commissioners especially as not all APC's will consider devices even though they can be prescribed on FP10 prescriptions in primary care. There have been no specific requests for it from specialists.

Purewick® is the first female external catheter to address the need for an effective, non-invasive method of managing urine output in women. It is an alternative to incontinence pads and indwelling catheters for female patients with urinary incontinence. An application for inclusion within the Drug Tariff to enable prescribing on FP10 is currently pending, and a decision is not expected before the end of 2020.

Currently evaluation data for the device is only available in conference abstracts/posters or unpublished evaluations carried out by individual hospitals. As yet there is no good quality published clinical evidence which directly compares the Purewick® External Female Catheter with indwelling catheter or incontinence pads. There is also currently no NICE guidance available on or which includes the use of the Purewick® device.

Purewick® may help to reduce urinary catheter days thus lowering the risk of Catheter Associated Urinary Tract Infection (CAUTIs). It was agreed any reduction in CAUTIs would be a benefit. Purewick® may also help to reduce the risk of moisture lesions/skin irritation from incontinence pads, and therefore reduce the associated risk of pressure ulcer damage by wicking away urine from the body. Evidence to support this comes largely from unpublished individual hospital evaluations of the product.

NTAG noted the offer the manufacturer to support a local evaluation/trial of the product in primary care and local nursing homes to gather further evidence of possible benefits/outcomes compared to urinary catheters and incontinence pads.

After discussion NTAG agreed not to recommend use of Purewick® on the NHS because there is a lack of quality evidence currently to support the efficacy of this device at this time to come to decision. NTAG agreed to review this recommendation if and when further

evidence becomes available, and to suggest to the CCGs that may wish to work with the manufacturer to evaluate the product further locally in a local product evaluation/trial.

ACTION: Secretary to draft recommendation as above

8) Review of NTAG Recommendations Greater Than Two Years Old

A paper summarising all the current NTAG recommendations and when they are due for review was presented by the secretary to identify those that may be out of date and require a review.

When NTAG was created in June 2014 it was agreed that only those recommendations that had substantial new evidence would be reviewed. The NTAG appeals process states that that an automatic re-review process is triggered 24 months post recommendation. Evidence searches are repeated and if new evidence/data than clinicians in the relevant speciality are asked if they wish the current NTAG recommendation to be reviewed.

The following fourteen recommendations have been identified as possibly requiring a review:

Title	Decision	Month	Year	Comment	Action agreed
Gastro-intestinal stimulation with the Enterra™ device for Gastroparesis (NETAG)	Not recommended	Apr	2010	NICE IPG489 May 2014 - allows use. 2004 version did not	Requires review
Tocilizumab (RoActemra®) for systemic-onset and polyarticular juvenile idiopathic arthritis (NETAG)		Jul	2010	Partially superseded by NICE TA	Archive as superseded by NICE TA and NHSE commissioned.
Stand-alone minimally invasive bipolar radiofrequency ablation for Atrial Fibrillation (NETAG)	Recommended	Jul	2011	NICE CG180 Aug 2014?	Requires review
Novel fentanyl products (Abstral®, Effentora®, Instanyl® and PecFent®): Updated appraisal for breakthrough pain associated with cancer (NETAG)	Not recommended	Jul	2011	Superseded by NHSE Items of Low Clinical Value which allows use in Palliative Care v2 June 2019	Archive as superseded by NHSE guidance
Airsonett® laminar flow device for treatment of uncontrolled allergic asthma	Not recommended	Apr	2015	Is new evidence. NHSE is commissioner in children	Requires review for any new evidence in adults
Teriparatide for atypical bisphosphonate induced fractures	Not recommended	Jun	2015	Check for new evidence needed	Requires review for any new evidence
Transanal Irrigation Systems (TAIs) for neurogenic bowel dysfunction, chronic constipation, and chronic faecal incontinence	Recommended	Apr	2016	NICE MTG36 Feb 2018. Update to say use cheapest product - no clinical review needed.	Update to reference MTG36
Erenumab and galcanezumab for prophylaxis of migraine	Not recommended	Nov	2018	NICE TA in progress	To archive once NICE TA published
Pitolisant (Wakix®) for the treatment of narcolepsy with or without cataplexy in adults	Recommended	Nov	2018	RMOC position statement in progress	Review once RMOC statement published
Daily vs on-demand PDE-5 inhibitors for management of erectile dysfunction following treatment for prostate cancer		Mar	2018	Need to check for any new evidence	Requires review for any new evidence
Anti-vascular endothelial growth factor therapies (bevacizumab or ranibizumab) as an adjunct to vitrectomy in diabetic retinopathy (NETAG)	Not recommended	Jul	2009	May be some new evidence published	To confirm with NE Retinal Group if review required

Bevacizumab (Avastin®) for neovascular glaucoma secondary to central retinal vein occlusion (NETAG)	Not recommended	Apr	2011		To confirm with NE Retinal Group if review required
Bevacizumab (Avastin®) or ranibizumab (Lucentis®) for macular oedema secondary to retinal vein occlusion(s)(NETAG)	Not recommended	Jan	2011		To confirm with NE Retinal Group if review required
Bevacizumab (Avastin®) for diabetic macular oedema (NETAG)	Not recommended	Jul	2012		To confirm with NE Retinal Group if review required
Intraocular telescope by VisionCare™ for age-related macular degeneration (NETAG)	Not recommended	Nov	2012	NICE IPG565 Sep 2016 - only within special arrangements for governance, audit and research	To confirm with NE Retinal Group if review required
Sequential pharmacological therapies in the management of macular oedema secondary to retinal vein occlusion	Recommended	Sep	2014		To confirm with NE Retinal Group if review required

After discussion NTAG agreed to add the recommendations identified and agreed as requiring review to its work plan over the next 12 months, and to contact ophthalmologists to clarify which recommendations relating to the eye require a review.

ACTION: Secretary to add recommendations requiring update or review to NTAG workplan.

ACTION: Secretary to contact NE Retinal Group to confirm which NTAG recommendations relating to the eye require a review.

9) Regional Medicines Optimisation Committee

No update on the Regional Medicines Optimisation Committees was available they have not met since February 2020 due to COVID-19. Their work plan and agendas can be found on the Specialist Pharmacy Services website.

10) NTAG Membership

a) Secondary Care vacancies

The secondary care vacancy has now been filled by South Tyneside and Sunderland NHS Foundation Trust. .

b) Primary care medicines vacancies

NT has now identified a deputy GP representative from Tees Valley CCG.

Post-meeting: CS added to membership as nominated deputy CCG finance representative.

ACTION: ID to identify deputy GP representative from County Durham CCG.

11) Work Plan.

The group discussed the work plan.

- Buprenorphine long acting injection (Buvidal®) – has been referred to RMOC South and so advised to wait to see what further guidance is issued nationally by them plus timescales for this.
- New drugs for wAMD (Brolucizumab) – NICE TA date to TBC – agreed to add to workplan for Sept 2020 (or sooner if RDTC can facilitate a rapid appraisal via an extra virtual meeting) as felt a regional approach would useful and NICE TA has been delayed due to Covid-19. Noted that Sunderland & South Tyneside APC have received a formulary application.
- Dupilumab and Omalizumab for chronic rhinosinitis with nasal polyps – added to Sept 2020 NTAG agenda provisionally as no NICE TA not expected until July 2021.
- SGLT2 in three diabetic cohorts – ASCVD, Heart failure and CKD – health economic monitoring work currently on hold due to Covid-19 and need to identify funding to do this work.
- Semaglutide oral – first oral GLP1 and not currently in NICE workplan. Agreed to add to workplan for Sept 2020 NTAG. Noted local interest from clinicians already.
- Andexanet alfa – review current NTAG recommendation if clinicians submit regional pathway/criteria for use but noted NICE TA now due in summer 2020 which will supersede current NTAG recommendation.
- Add those recommendations greater than two years old identified and agreed as requiring review under agenda item 8.

Also agreed to add six monthly review of prescribing data for current NTAG recommendations to September 2020 NTAG agenda provisionally.

12) NTAG Annual Report June 2020 - draft

NTAG Annual Report for 2019/20 was presented to and approved by the group subject to inclusion of a few words around the role of the new patient representative.

ACTION: Secretary to send NTAG Annual Report 2019/20 to Northern CCG Joint Committee

13) AOB

Andrea Loudon informed the group this was her last NTAG meeting as she is retiring next month. The Chair thanked her for valued contributions to NTAG since its formation. It is hoped her replacement will take up her place on NTAG.

No other business was raised and the meeting concluded.

The date of the next meeting was agreed to be 1st September 2020 and will be held virtually via StarLeaf.

Minutes produced by G Mankin, Professional Secretary to NTAG, 2nd June 2020