North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 9th July 2013 at Northumbria House, Cobalt Business Park, North Tyneside

Present

Anne-Marie Bailey	Senior Medicines Optimisation Pharmacist	NECS
Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Sue Dickinson	Director of Pharmacy	RDTC
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Janet Kelly	Chief Matron for Community Services	NHCT
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Peter McEvedy (PMcE)	GP and Prescribing Lead	NHS Northumberland CCG
Tamsin Oswald (TO)	Consultant Microbiologist	NHCT
John Ross (JR)	Patient Representative	
Helen Seymour	Senior Medicines Optimisation Pharmacist	NECS
Simon Thomas	Consultant Clinical Pharmacologist	NUTH
Susan Turner (STu) (Professional Secretary)	Medicines Optimisation Pharmacist	NECS
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NHCT/NHSE
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Ian Campbell (IC)	Assistant Director of Pharmacy	NUTH
Helen Coundon	GP and Prescribing Lead	NHS North Tyneside CCG
Matt Grove	Consultant Rheumatologist	NHCT
Alexander Dyker	Consultant Physician	NUTH
Sue Gordon (SG)	Consultant in Public Health	NHS England
Wendy Ross	GP and APC Representative	NHS Newcastle North & East CCG
Nicola Weaver	GP and Prescribing Lead	NHS Newcastle West CCG

In attendance

David Scott	Lead technician	NUTH

NoT LPC	North of Tyne Local Pharmaceutical Committee
NHSE	NHS England
NHCT	Northumbria Healthcare NHS Foundation Trust
NECS	North of England Commissioning Support Organisation
NTWT	Northumberland Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre

2013/54 Declarations of interest

No relevant declarations made.

2013/55 Appeals

There were no appeals to be heard.

2013/56 Minutes and decision summary from the meeting held on Tuesday 14th May 2013.

These were accepted as a true record.

2013/57 Matters arising.

2013/34 – Following the positive NICE TAG for apixaban in the prevention of non-valvular AF Dr Skinner was asked to convene a group which would allow wider clinical dialogue with respect to the relative merits of the use of all the NOAC compared to each other and in comparison to warfarin. It should be noted that this meeting was about which drugs to use once a decision had been reached that a patient with non-valvular AF be anti-coagulated and not about recommendations for whether patients are anti-coagulated.

A report from the group has now been received and the following steps will now be taken:

- The APC summary information table of NOACs will be updated by the RDTC to include apixaban, and update the drug interactions section. This summary table will be a high level source of information for prescribers and not an algorithm directing them to choose one agent over another.
- As an introduction to the summary table above a list of key factors which influence the choice between warfarin and NOACs and between different NOACs, as well as additional guidance about what to do in primary care in the event of bleeding will be produced for use by all clinicians considering initiation of an anticoagulant. This will also be produced by the RDTC. Once this is produced the current document on the APC website relating to dabigatran will be removed.
- Bleeding risk and the potential need for reversal, as well as recommendations for regular review, particularly in patients with reduced renal function, will need to be incorporated into the above list of factors to consider when making a decision about which drug to use.
- A patient decision aid should be produced that all prescribers can use when discussing the relative risks and benefits of agents with patients. Work is already underway on this and NW will liaise with the authors and share outcomes with APC members.
- A North of Tyne patient held card incorporating relevant information which all patients being treated with a NOAC should be given, and which should be used in preference to those developed by a pharma company, will be produced. NW agreed to discuss the development of this with colleagues within NUTH who are already currently working on a decision aid for clinicians to use with patients. The patient held card needs to include information for patients about what to do in the event of an acute bleed. In the interim current practice with the use of a pharma-based card is reasonable.
- INR services should provide information to primary care and secondary care clinicians if relevant, if TTR is low. Commissioning representatives on the APC will ensure that their organisations are aware of the benefits of including this recommendation in any contract renegotiation/procurement for INR services.
- All documents produced will come back to the APC for approval before use.

Discussion ensued on the relative positioning of the newer agents in the formulary

- warfarin is currently listed as the first line agent. The committee felt this could no longer be supported in line with the NICE TAGs for the newer agents so this prioritisation will be removed. The correct use of the previously mentioned decision aids will help inform the choice of appropriate agent on an individual patient basis.

2013/58 Report from the Formulary Sub-committee

Formulary version 4.4 is now available on the APC website.

Minutes and recommendations from the meeting held on 17th June 2013.

The above minutes and recommendations were received by the committee.
The summary of decisions made by the committee on new product requests is listed in **Appendix 1**.
The following specific points were highlighted for further consideration:

Lisdexamfetamine

The request for lisdexamfetamine dimesylate for the treatment attention deficit/hyperactivity disorder (ADHD) in children aged 6 and over years of age when response to previous methylphenidate treatment is considered clinically inadequate was previously deferred whilst the views of clinicians from NTW were sought. This has now been received however some outstanding concerns remain that still need addressed before approval can be given.

Decision: Deferred
Clarification on what defines an adequate course of methylphenidate, what constitutes an inadequate response to that course of methylphenidate and the criteria for defining review periods following initiation of lisdexamfetamine is still required and needs to be agreed with specialists across the area before approval can be given If approved it should be a Shared Care drug and only prescribed by GPs after an initial trial of therapy with evidence of benefit, as assessed by a specialist.

Linaclotide

Linaclotide has been requested for the symptomatic treatment of moderate-to-severe irritable bowel syndrome with constipation (IBS-C).
This treatment is relatively expensive and there have been no head to head trials with the other treatments routinely used in IBS-C. There may be a small number of patients with particularly severe features resistant to other treatments that might benefit from Linaclotide but further confirmation of the criteria used (a) to select patients for a therapeutic trial and (b) to define a beneficial response is needed. The applicant has submitted a guideline addressing some of these concerns and this needs to be duly considered and approved before the product is made available through the formulary.

Decision:Deferred.
The request for linaclotide should be deferred to allow the formulary subcommittee time to consider the additional information provided.

Tapentadol

Tapentadol has been requested for adults with severe pain who have been screened for a neuropathic element to their pain and are uncontrolled or experiencing GI side effects on existing therapy. A previous request for tapentadol had been rejected by the committee.

It was acknowledged that this is a difficult to treat group of patients however the committee was not convinced that there is a place for tapentadol within the Formulary due to the lack of strong evidence of additional benefit over currently available therapies.

Decision:Refused
The request for tapentadol for the treatment of severe chronic pain with a neuropathic element should not be approved.

Minocycline – Rheumatoid arthritis
Minocycline has been requested for the treatment of rheumatoid arthritis. It was noted that this is an unlicensed indication. It has been requested for use in a specific subset of patients who are unable to tolerate biologics and other DMARDs; as with all DMARDs treatment will be monitored and stopped if no response is shown.
The FSC had deferred their decision until the views of microbiologists at NUTH and Northumbria had been sought and whilst confirmation that the application had support from specialists across both acute trusts was sought. These reassurances have now been given.

Decision: Approved
The request for minocycline for the treatment of rheumatoid arthritis in patients where alternative treatments are contraindicated was approved.

The FSC minutes state that there are often requests to change the Formulary in light of changes in DH advice as found in the Green Book. The FSC therefore wish the committee to support having a statement in the Formulary that directs clinicians to follow the latest advice given in the Green Book regarding the requirement for specific preparations. The formulary will continue to be updated accordingly but this would ensure that prescribers are always aware that the Green Book takes precedence.
NB. As this was not discussed at the meeting, Chairs action was taken following the meeting to approve this proposal.

2013/59 Report from the Medicines Guidelines and Use Group

In May (Agenda Items 2013/40 and 2013/44) there had been a proposal that the QIPP subgroup of the APC evolve to become a Medicines, Guideline and Formulary Review Group which could take on some of the outstanding roles of the QIPP MM board, with an additional focus on guidelines and ongoing review of medicines in use e.g. formulary compliance/audit. It was also agreed that the Shared Care Group would cease to meet and the work previously undertaken by that group would come under the remit of this new group.

The first meeting of the Medicines Guidelines and Use Group has now taken place and draft terms of reference were received and approved.

HS highlighted the following points from the draft minutes of 19/6/13:

- Guidelines that the committee were asked to endorse:
  - Infant milk guideline - endorsed
  - Prescribing Guidelines for Stoma Accessories (Adult) – endorsed. It

was noted that there is some additional work underway with regards to stoma prescribing and guidance relating to third party ordering.

- APC Guidelines and Statements for review plus Blue information sheets and Shared Care Agreements – these will now be considered by this group. A number are due for updating and HW agreed to contact the original authors to expediate this process.
- Traffic Light List version 4.0 May 2013 – updated on the website

It was also noted that there have been occasional decisions taken where some members may have felt that niche groups of patients were being denied medicines because of a concern for wider adoption across the healthcare economy than intended in the application. The MGUG group will take on responsibility for the monitoring of the rate of uptake of some medicines following approval where the APC has flagged a potential for use beyond the original approval.

2013/60 Report from the Anti-microbial Chemotherapy subcommittee.

No report is due.

2013/61 Terms of reference

A revised draft of the Terms of Reference was received and approved.

2013/62 Documents previously circulated by e-mail

None

2013/63 Buccal Midazolam

Until recently, only unlicensed midazolam products were available for administration via the buccal route. The preferred and most commonly used unlicensed product is Epistatus (10mg/ml) which is available on the North of Tyne formulary. A licensed product, Buccolam®, is now available. It is licensed for status epilepticus in children aged 3 months to 18 years.

Decision : Approved
Buccolam® will be added to the formulary and should be used within its licensed indications as the preferred product. A coordinated active switching programme in appropriate patients will be facilitated with the input of the appropriate specialist teams.

Epistatus will still be used for pre-sedation in secondary care for palliative care. It may also still be required in some paediatric and adult epilepsy patients depending on clinical need.

2013/64 Erectile Dysfunction

The patent on Viagra expired in June and several companies are already launching generic versions of the drug.
As CCGs are anxious to capitalise on the expected price reduction to around £1 per tablet the committee was asked to consider the recommendation that sildenafil should now be the sole approved first-line phosphodiesterase type-5 inhibitors.
NHS drug tariffs could take some months to stabilise, but it is expected that these price reductions will be reflected in the drug tariff within a few months.
Tadalafil and vardenafil are still patent protected and generic versions of either of these drugs will not be available before 2017.

Decision: Approved
Sildenafil will be positioned as the "first – line agent" in the formulary. Tadalafil and vardenafil will currently remain on the formulary as alternative options but evidence clarifying the particular group(s) of patients who may benefit from second line agents will now be sought.

The secretary will write to the lead specialist of sexual health services in NUTH to inform her of this decision. SC agreed to liaise with the specialists within NHCT.

2013/65 NICE

The following NICE TAGs were noted. The recommendations within them were endorsed by the committee and the North of Tyne Formulary will be updated to reflect these decisions.

NICE Technology Appraisals published in May and June

- TA283 - Macular oedema (retinal vein occlusion) - ranibizumab
- TA284 - Bevacizumab in combination with paclitaxel and carboplatin for first-line treatment of advanced ovarian cancer - negative appraisal
- TA285 - Ovarian, fallopian tube and primary peritoneal cancer (recurrent advanced, platinum-sensitive or partially platinum-sensitive) - bevacizumab - negative appraisal
- TA286 - Schizophrenia or bipolar disorder - loxapine inhalation (terminated appraisal due to lack of submission)
- TA287 - Pulmonary embolism and recurrent venous thromboembolism – rivaroxaban
- TA288 - Type 2 diabetes - Dapagliflozin combination therapy
- TA289 - Myelofibrosis (splenomegaly, symptoms) - ruxolitinib - negative appraisal.
- TA290 - Overactive bladder - mirabegron
- TA291 - Gout (tophaceous, severe debilitating, chronic) – pegloticase - Negative appraisal.

All approved products will be added to the North of Tyne formulary in line with the NICE TAGs.

2013/67 Chair's action

None taken

2013/68 Any other business

1. SW informed the committee that following the expected licence approval for a s/c version of trastuzumab NHS England will be requesting that all Trusts consider switching use to this formulation for breast cancer treatments. The formulary will therefore need to be changed at that point to reflect this position. He will keep the committee informed.

2. Trazodone shortages – TD informed the committee that NTW had drafted a document designed to help prescribers and pharmacists make informed decisions when faced with the need to make changes in medication where current supply chain shortages were causing a problem. The committee acknowledged the expertise of the authors and agreed that, once the finalised version had been received by the secretary, she would forward it to members to enable them to share with their organisations as appropriate.

2013/69 Date and time of next meeting

Tuesday 10th September 2013 at 12:30pm
Room 3, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.

Signed: ..... Date: 10/9/13

(Chair of the APC)

North of Tyne
Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 9th July 2013.**

Classification of products:

R = 'RED' drugs for hospital use only
A = 'AMBER' drugs suitable for use under Shared Care arrangements
B = 'BLUE' drugs initiated in secondary care where an information sheet for GPs is recommended
T = 'RED' drugs used in Tertiary Care only.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
Botulinum Toxin A – Bladder dysfunction in paediatrics [u]			√	Botulinum toxin A is currently included in the Formulary (for adult patients) for the treatment of overactive bladders in patients who have failed to respond to conservative treatment. This is an unlicensed indication. It has now been requested for this indication in paediatric patients. Further detail relating to a treatment pathway is still required. **Bladder dysfunction(paediatrics)** – awaiting further detail before decision can be made.
Lisdexamfetamine (Elvanse®) - 30mg, 50mg and 70mg capsules			√ A	Lisdexamfetamine dimesylate (Elvanse®) has been requested for the treatment of ADHD in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate. It has the advantage that it can be used once daily and has a lower abuse potential compared to standard dexamfetamine. **Decision: Deferred** Clarification on what defines an adequate course of methylphenidate, what constitutes an inadequate response to methylphenidate and the criteria for defining review periods following initiation of lisdexamfetamine is required and needs to be agreed with specialists across the area. If approved it should be a Shared Care drug and only prescribed by GPs after an initial trial of therapy with evidence of benefit, as assessed by a specialist.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
DC beads - 75-150 micron	√			100–300 micron DC beads have been on the Formulary for several years for the treatment of malignant hypervascularised tumour(s) using the TACE procedure. DC beads 75-150 micron have been requested on the grounds that a smaller bead size could allow more of the intended drug, usually doxorubicin or irinotecan, to be delivered to the tumour. Further evidence provided by the applicant to support the use of DC beads had been received and the committee was satisfied that this provided evidence of benefit. **Decision:** 75-100 micron DC beads were approved and will be added to the formulary in addition to the 100-300 micron DC beads.
2) New Requests				
Linaclotide (Constella®) - 290 microgram capsules			√	Linaclotide has been requested for the symptomatic treatment of moderate-to-severe irritable bowel syndrome with constipation (IBS-C). This treatment is relatively expensive and there have been no head to head trials with the other treatments routinely used in IBS-C. There may be a small number of patients with particularly severe features resistant to other treatments that might benefit from Linaclotide but further confirmation of the criteria used (a) to select patients for a therapeutic trial and (b) to define a beneficial response is needed. If approved for use it would be for specialist initiation only.
Tapentadol (Palexia®) - 50mg, 100mg, 150mg, 250mg and 250mg MR tablets, 50mg and 75mg IR tablets		√		Tapentadol has been requested for adults with severe pain who have been screened for a neuropathic element to their pain and are uncontrolled or experiencing GI side effects on existing therapy. The committee noted the available evidence of clinical efficacy and adverse effects, but was not convinced that there is a place for tapentadol within the Formulary due to the lack of strong evidence of additional benefit over currently available therapies in this group of patients. **Decision:** The request for tapentadol for the treatment of severe chronic pain with a neuropathic element was not approved.
3) New formulations & extensions to use				
Methylphenidate MR (Medikinet XL®) - 5mg, 10mg, 20mg, 30mg and 40mg MR capsules.	√			Methylphenidate MR (Medikinet XL®) has been requested for treatment of ADHD in children aged six years and over on the grounds that it provides an effective and cheaper alternative to the other MR Methylphenidate preparations on the Formulary, and that its inclusion in the Formulary would allow a more effective match between the clinical and temporal profiles of ADHD in different patient groups than is currently possible. **Decision:** The request for Medikinet XL® was approved.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Minocycline [u] – DMARD	√			Minocycline has been requested for the treatment of rheumatoid arthritis; this is an unlicensed indication. It has been requested for use in a specific subset of patients who are unable to tolerate biologics and other DMARDs. Microbiologists from both acute trusts have confirmed that such use would not cause concerns to them. **Decision:** The request for minocycline for the treatment of rheumatoid arthritis in patients where alternative treatments are contraindicated was approved.
Abatacept SC (Orencia®) 125mg injection	√			Abatacept SC has been requested for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to previous therapy with one or more DMARDs including methotrexate, or for patients who have failed on a tumour necrosis factor (TNF) alpha inhibitor. **Decision:** The request for SC abatacept was approved and its use should be in line with the current NICE TAGs for the IV preparation.
Pregabalin (Lyrica®) 20mg/ml solution	√			A 20mg/ml pregabalin solution is now available for those patients who require a liquid preparation. It was noted that the licensed liquid preparation is cheaper, per mg, up to the 100mg capsules. **Decision:** Pregabalin solution will be added to the Formulary.
Omeprazole 40mg injection	√			Omeprazole injection is available at the same price as the omeprazole infusion. **Decision:** IV omeprazole will be included in the Formulary.
4) Products considered by NESCG and decisions endorsed by APC				
None				
5) Products considered by NICE				
TA283 - Macular oedema (retinal vein occlusion) - ranibizumab	√			Approved. The formulary will reflect the NICE TAG.
TA284 - Bevacizumab in combination with paclitaxel and carboplatin for first-line treatment of advanced ovarian cancer.		√		Negative appraisal

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA285 - Bevacizumab - Ovarian, fallopian tube and primary peritoneal cancer (recurrent advanced, platinum-sensitive or partially platinum-sensitive)		√		Negative appraisal
TA286 - loxapine inhalation - Schizophrenia or bipolar disorder		√		Terminated appraisal due to lack of submission
TA287 – rivaroxaban - Pulmonary embolism and recurrent venous thromboembolism	√			Approved. The formulary will reflect the NICE TAG.
TA288- Dapagliflozin combination therapy - Type 2 diabetes	√			Approved. The formulary will reflect the NICE TAG.
TA289- ruxolitinib - Myelofibrosis (splenomegaly, symptoms)		√		Negative appraisal.
TA290 - mirabegron - Overactive bladder	√			Approved. The formulary will reflect the NICE TAG.
TA291 – pegloticase - Gout (tophaceous, severe debilitating, chronic)		√		Negative appraisal.
6) Appeals against earlier decisions by the APC				
None				
7) Miscellaneous decisions by the APC				
Sildenafil – first line use in erectile dysfunction	√			Following the patent expiry on sildenafil and subsequent cost savings available the APC confirmed that sildenafil will be positioned as the “first – line agent” in the formulary. Tadalafil will currently remain on the formulary as an alternative option but evidence clarifying the particular group(s) of patients who may benefit from second line agents will now be sought.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Buccolam® (buccal midazolam) 5mg/ml, 2.5mg,5mg, 7.5mg and 10mg prefilled oral syringes for the management of status epilepticus	√			Until recently, only unlicensed midazolam products were available for administration via the buccal route. The preferred and most commonly used unlicensed product is Epistatus (10mg/ml) which is available on the North of Tyne formulary. A licensed product, Buccolam®, is now available. It is licensed for status epilepticus in children aged 3 months to 18 years. **Decision**: Buccolam® will be added to the formulary and should be used within its licensed indications as the preferred product. A coordinated active switching programme in appropriate patients will be facilitated with the input of the appropriate specialist teams. Epistatus will still be used for pre-sedation in secondary care for palliative care. It may also be required in some paediatric and adult epilepsy patients depending on clinical need.