North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 11th March 2014 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
Ian Campbell (IC)	Assistant Director of Pharmacy	NUTH
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Helen Coundon	GP and Prescribing lead	NHS North Tyneside CCG
Sue Dickinson	Director of Pharmacy	RDTC
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Matt Grove	Consultant Rheumatologist and Head of Service	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	
Wendy Ross	GP and APC Representative	NHSNewcastle North & East CCG
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	Consultant Pharmacist in Cancer Services	NHCT/NHSE
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Sue Gordon (SG)	Consultant in Public Health	NHS England
Janet Kelly	Chief Matron for Community Services	NHCT

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

2014/15 Declarations of interest

AMB declared an interest with regards to Pixanthrone - husband employed by the company responsible for this product.

2014/16 Appeals

No appeals.

2014/17 Minutes and decision summary from the meeting held on Tuesday 14th January 2014.

These were accepted as a true record.

2014/18 Matters arising not on the agenda.

N-TAG. Membership had been circulated. The RDTC are providing professional secretary support to the group and LDM groups will receive copies of the minutes for information. Recommendations from N-TAG will go to the CCG Forum quarterly for ratification.

Previous advice received by the committee in regards of safety advice relating to strontium has now changed. The new advice will be incorporated in formulary and guideline recommendations moving forward.

2014/19 Action Log

The action log was reviewed and will be updated to reflect the following progress:

- Newer Oral Anticoagulants – SD confirmed that NICE intends to publish a Patient Decision Aid in June and therefore local work on this will not now progress.
- Tapentadol – A single information sheet emphasising the formulary position is being produced for attachment to clinic letters. Work on this is still progressing.
- Lisdexamfetamine shared care guideline – This has gone to NTWT for comments.
- Linaclotide blue information sheet – presented today for consideration (see 2014/22).
- Medicine Administration Aids Support Tool – ML agreed to circulate this to members.
- Branded generics - An umbrella statement has now been added to the formulary that allows branded generics to be used, in accordance with APC guidance, without them being formally listed in the formulary.

2014/20 Election of officers

The committee's terms of reference require a review of officers for the North of Tyne APC every 3 years. This period has now elapsed.

No proposals for consideration of new officers had been received for consideration following such request and therefore the existing officers were re-elected for a further 3 years.

The officers for 2014-2017 are:

- Chair – David Campbell
- Vice chair – Simon Thomas
- Professional secretary – Susan Turner

Sub-groups of the Committee will elect/re-elect their own officers in line with their TORs.

2014/21 Report from the Formulary Sub-committee

Formulary version 5.1 is now available on the APC website.

Minutes and recommendations from the meeting held on 11th February 2014.

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:

NuvaRing® vaginal delivery system
NuvaRing® is a combined hormonal contraceptive inserted once a month at the beginning of the cycle and removed after 3 weeks to give a 7 day hormone free period. Pregnancy data and compliance data shows no strong evidence of it being any better or worse than other combined contraceptives, however the vaginal delivery method avoids first pass metabolism, allowing lower doses to be administered and gives better cycle control. NuvaRing® has been requested by New Cross Sexual Health Centre for those patients who cannot tolerate oral or transdermal contraceptives. Cost effectiveness was demonstrated in women who chose to discontinue oral contraceptives but had not been proven as a first line agent. The FSC had noted that overall it was appropriate for a very small number of patients and that adding it to the formulary could encourage its use beyond this group of patients with specific concerns raised about company sponsorship.

After discussion the committee agreed that the NuvaRing® should be added to the formulary for the specific group of patients outlined in the application but only following specialist initiation.

Decision: NuvaRing®
Approved only for those patients who cannot tolerate oral or transdermal contraceptives following specialist recommendation.

NICE CG171: Urinary incontinence in women
This Guideline recommends oxybutinin immediate release (IR), tolterodine IR and darifenacin as first choice agents. This recommendation from NICE was based on cost effectiveness of the available options. It was noted that that the NICE guideline referred solely to women. Initial recommendations by the FSC were that the committee should give consideration to adding darifenacin and removing solifenacin, trospium, fesoterodine and tolterodine MR capsules from formulary. Feedback had been requested from the urologists but this had not yet been received, although the committee was informed that this was expected before the next FSC meeting. As an interim measure it was agreed that oxybutinin immediate release (IR) and tolterodine IR would now become the 2 agreed first line formulary choices but that a decision regarding the positioning of the other agents would be made following the April FSC meeting.

Decision: oxybutinin immediate release (IR) and tolterodine IR are the first line formulary choices for the treatment of urinary incontinence.

Vitamin B compound strong (nicotinamide 20mg, pyridoxine hydrochloride 2mg, riboflavin 2mg & thiamine hydrochloride 5mg per tablet)
A request for removal of this product had been submitted by commissioners as it is no longer considered appropriate use of NHS resources in the treatment of, Wernicke's encephalopathy and Korsakoff's psychosis, especially as seen in chronic alcoholism. These patients are best treated initially by the parenteral administration of B vitamins (Pabrinex®), followed by oral administration of thiamine in the longer term. There remains a small role in refeeding syndrome (hospital use only).

Decision: Vitamin B Co Strong will become a Red drug for short term use in refeeding syndrome. Use in people at high risk of developing, or with suspected, Wernicke's encephalopathy is no longer supported.

2014/22 Report from the Medicines Guidelines and Use Group

Minutes from the meeting of 15/01/14 were accepted and the following actions taken:

Guidelines for approval:

- Guidelines for the diagnosis and management of epilepsy in primary and secondary care – approved.
- Guidelines for the Monitoring of Immune Modifying Drugs (IMDs) in Stable Adult Patients (excluding post transplantation) in Primary and Secondary Care - approved
- Guidelines for the management of common urological conditions in adults ≥ 18 years – the committee were informed this guideline would be brought back to a subsequent meeting for approval.

Information leaflets for primary care for approval :

- Linaclotide - not approved. Clarity was needed in the information leaflet in terms of the agreed place in therapy of this agent. ML agreed to take these proposed changes back to the MGUG.
- Modafinil – update - approved
- Retigabine – update - approved
- Rosuvastatin – update - approved
- Triptorelin (Decapeptyl SR), Use in the Management of Precocious Puberty – update – discussion took place around the allocation of Blue status for this product in one indication but not in others. It was agreed that this was appropriate as this use was for an unlicensed use in children - approved
- Lanreotide and Octreotide –Treatment of Adults with acromegaly or neuroendocrine tumours - update - approved

Shared Care Guidelines :

- Immunosuppressive Treatment following Paediatric renal transplantation - approved.
- Immunosuppression for children with nephrotic syndrome – deferred. ML informed the group that these still had to go back through MGUG.
- Dexamfetamine (Dexamphetamine) in the Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children and young people – approved.
- Methylphenidate in the Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults – query raised around the requirement for a 3 month period of stabalisation before primary care accept prescribing being misleading in terms of the currently commissioned service. It was agreed that as there is also a phrase allowing for case by case consideration the guideline could be approved as presented – approved.
- Methylphenidate in the Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children and young people and for Giggle Incontinence in children aged 8 to 16 years - approved
- Naltrexone – approved.

C Diff Assessment Tool – A request was made to move the position of the PPI statement higher up the document to emphasise that the appropriateness of continued use of PPIs whilst on an antibiotic should be

considered early on in treatment. Further minor changes were suggested out with the meeting and therefore the chairman agreed that once the changes are made by the author the document will be recirculated to members for approval.

A request to change the status of fidaxomicin from Red to "initiated on the recommendation of a consultant microbiologist" was accepted.

Updated traffic light list (01/14)uploaded on website

2014/23 Report from the Anti-microbial Chemotherapy subcommittee.

No report due.

The group discussed the potential for this group to delegate work to a new regional group to allow consistency on a wider geographical footprint. This was accepted in principle but it was recognised that there was a balance between consistency and the need for local variation based on resistance patterns. The group decided to work with the newly formed regional group and reconsider their position in a few months' time.

2014/24 Documents previously circulated by e-mail

The chairman had previously circulated a letter received from Mr. Chris Piercy on behalf of the Newcastle Gateshead Alliance Optimisation of Medicines, Pathways & Guidelines Committee.

The letter outlined concerns that the Alliance had regarding the content and commissioning implications of the North of Tyne NOAC guidance which was recommended for approval in September 2013. The Alliance committee members acknowledged that the guideline is a useful and informative document in supporting GPs to make informed decisions with their patients but expressed concern that it could be open for misinterpretation. The document contains a section headed "When might warfarin be the preferred option?" and Mr. Piercy suggested that this may infer (by omission of a similar section for NOACs) that these newer drugs are considered the first line option rather than being given equal status with warfarin as defined by the formulary position. Mr. Piercy is therefore requesting a review of the front page of the guideline and also of the formulary position of the NOACs in order to specify a preferred NOAC based on the most cost effective option taking into account the availability of primary care rebate schemes. The details of these are commercial in confidence but, unless there is a specific clinical need to use one particular agent, the more cost effective NOACs should be recommended. Mr. Piercy would like endorsement of Rivaroxaban as the preferred option as it is a once daily dose and can be dispensed in a monitored dosage system.

Before the committee discussed the letter the chairman raised the following points:

- It was noted that Gateshead CCG is not currently a member of the North of Tyne APC.
- The APC Terms of Reference outline the process for making recommendations.
- Active representation from members ensures that decisions are only made following full discussion of any concerns at that time. It is hoped that such concerns would be flagged at a more appropriate point in decision making in the future. Ideally this would be achieved by having relevant members around the APC table representing all organisations to which the guidance applies.
- Obviously, irrespective of where feedback comes from, if there is any risk of misinterpretation of guidance issued by the committee, then the committee should seek to address that.
- Before making the recommendations in relation the NOACs the committee

gave long and detailed consideration of whether to have a preferred order and the legal position in relation to products approved through the NICE Technology Appraisal process.

The committee agreed that the document would be amended to strengthen the requirement for informed discussion between clinician and patient before any decision is made to start a NOAC. In terms of preferred choices the committee stands by its decision to list all equally in the formulary, in order to comply with its understanding of NICE Guidance. With regards to primary care rebate schemes, a CCG could choose to flag these to members if they so wished but the APC would refrain from such direction.

The chairman will respond to Mr. Piercy in writing.

2014/25 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 January and February

- TA303 Multiple sclerosis (relapsing) – teriflunomide – recommended as a possible treatment for adults with active relapsing-remitting multiple sclerosis that isn't highly active or rapidly evolving severe relapsing-remitting multiple sclerosis. NHS England is the responsible commissioner.
- TA305 Macular oedema (central retinal vein occlusion) - aflibercept solution for injection are recommended as a possible treatment for people with sight problems caused by macular oedema from central retinal vein occlusion.
- TA306 Lymphoma (non-Hodgkin's, relapsed, refractory) - pixantrone monotherapy is recommended as a possible treatment for adults with multiply relapsed or refractory aggressive non-Hodgkin's B cell lymphoma if:
    - they have previously been treated with rituximab and
    - they are having third or fourth-line treatment

2014/26 NHS England Specialised Services Approval

The following NHS England Specialised Service Approvals were noted:

- Cancer Drugs fund Feb 2014
- SSC1404 - Teriflunomide - funded from 23/4/14
- SSC1405 - Repatriation of transplant patients.
- SSC1406 - Plerixafor for stem cell mobilisation (update)
- SSC1411 - Pixantrone monotherapy for treating multiply relapsed or refractory aggressive non-Hodgkin's B-cell lymphoma

The recommendations and commissioning intentions within them were noted by the committee and the North of Tyne Formulary will be updated to reflect these.

2014/27 Chair's action

An Update to the dressings section of the Formulary was approved following appropriate consultation.

2014/28 Any other business

Domperidone – specialists in respective organisations will be asked by ML and SC to consider the advice with regards to infant feeding in light of a recent MHRA safety alert.

2014/29 Date and time of next meeting

Tuesday 13th May 2014 at 12:30pm

Room 3, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.

Signed: ..... **Date:** 13/5/14

(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 12th March 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

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
Granisetron 3.1mg/24 hours transdermal patches (Sancuso®)				Granisetron patches had previously been requested for use in patients to prevent chemotherapy induced nausea and vomiting in multi-day chemotherapy regimens to replace palonosetron capsules. The request for granisetron patches was deferred until the matter was discussed at the cancer network clinical group meeting in February 2014.The network group did not support addition to formularies and the applicant has since withdrawn the request.
Vitamin B compound strong (nicotinamide 20mg, pyridoxine hydrochloride 2mg, riboflavin 2mg & thiamine hydrochloride 5mg per tablet)				A request for removal of this product had been submitted by commissioners as it is no longer considered appropriate use of NHS resources in the treatment of Wernicke's encephalopathy and Korsakoff's psychosis, especially as seen in chronic alcoholism. **Decision**: Vitamin B Co Strong will become a Red drug for short term use in refeeding syndrome. Use in people at high risk of developing, or with suspected, Wernicke's encephalopathy and Korsakoff's psychosis, especially as seen in chronic alcoholism , is no longer supported as these patients are best treated initially by the parenteral administration of B vitamins (Pabrinex®), followed by oral administration of thiamine in the longer term.
2) New Requests				
NuvaRing® vaginal delivery system	✔			NuvaRing® is a combined hormonal contraceptive vaginal ring. It is inserted, by the patient, for 21 days and then removed for a 7 day hormone free period. It was noted that it was no more or less effective than other combined contraceptives. It was noted that this method of contraception would be appropriate for a very small number of women. **Decision:** The requests for NuvaRing® was accepted for use in patients who are unable to tolerate progesterone-only contraceptives, have experienced skin irritation with the transdermal patch, and are unable to take oral contraceptives due to allergy. Use should be initiated by a specialist in contraceptive services.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
3) New formulations & extensions to use				
None				
4) Products considered by NESCG and decisions endorsed by APC				
SSC1406 - Plerixafor for stem cell mobilisation (update)	✓			The formulary will reflect the NHS England Specialised Services circular position.
5) Products considered by NICE				
TA303 Multiple sclerosis (relapsing) – teriflunomide	✓			Teriflunomide is recommended as a possible treatment for adults with active relapsing-remitting multiple sclerosis that isn't highly active or rapidly evolving severe relapsing-remitting multiple sclerosis. NHS England is the responsible commissioner. The formulary will reflect the NICE approval noting NHS England SSC1404 - Teriflunomide - This will be funded from 23/4/14.
TA305 Macular oedema (central retinal vein occlusion	✓			Aflibercept solution for injection is recommended as a possible treatment for people with sight problems caused by macular oedema from central retinal vein occlusion. The formulary will reflect the NICE approval.
TA306 Lymphoma (non-Hodgkin's, relapsed, refractory) - pixantrone	✓			Pixantrone monotherapy is recommended as a possible treatment for adults with multiply relapsed or refractory aggressive non-Hodgkin's B cell lymphoma if: ○ they have previously been treated with rituximab and ○ they are having third or fourth-line treatment The formulary will reflect the NICE approval.
6) Appeals against earlier decisions by the APC				
None				
7) Miscellaneous decisions by the APC				
Ipratropium bromide MDI	✓			Request to change the status of ipratropium inhaler from first line formulary choice. Evidence now supports the use of long acting antimuscarinic agents for treating COPD. **Decision:** Ipratropium should no longer be first choice for the treatment of COPD.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Hydroxychloroquine tablets	✓			Hydroxychloroquine is on formulary as a B drug but currently no information sheet is available. It was suggested that prescribers could be directed to the NoT DMARD guidelines. After discussion it was felt an information sheet would be more appropriate. **Decision:** An information sheet is to be produced and considered at the next MGUG meeting.
Omega 3 fatty acids – NICE CG172				CG172 does not recommend omega 3 fatty acids for secondary prevention of MI. They will be retained for use in the treatment of hypertriglyceridemia following specialist advice.
Sodium fluoride 0.05% dental rinse	✓			Department of Health guidelines recommend the use of sodium fluoride 0.05% dental rinse in children over 7 years with concerns of caries. **Decision:** Sodium fluoride 0.05% dental rinse should be approved for addition to the formulary for use within the dental hospital .
NICE CG171: Urinary incontinence in women				This guideline recommends darifenacin, oxybutinin immediate release (IR) and tolterodine IR as first choice agents for urinary incontinence in women. Until a final review is undertaken, including the consideration of the use of these medicines in men, tolterodine and oxybutynin immediate release preparations will be the first line formulary choices for urinary incontinence. The FSC will be asked to review the position of solifenacin, trospium, fesoterodine and tolterodine MR as well as considering the addition of darifenacin following review of additional evidence to be presented by the urology specialists.
NICE CG173: Neuropathic pain - pharmacological management				This guideline highlights that tramadol is not recommended for long term neuropathic pain control although it can be used for short term rescue therapy. Carbamazepine is also on formulary as a treatment for neuropathic pain, however the new NICE guideline clearly states that it should be used for trigeminal neuralgia only. **Decision:** Tramadol will be removed from the neuropathic pain section of the formulary and a statement added to the effect that carbamazepine should be used for trigeminal neuralgia only.