North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 14th January 2014 at Northumbria House, Cobalt Business Park, North Tyneside

Present:

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
Matt Grove	Consultant Rheumatologist and Head of Service	NHCT
Matt Haggerty	Governance and Audit Pharmacist (on behalf of Tim Donaldson)	NTWT
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Peter McEvedy (PMcE)	GP and Prescribing Lead	NHS Northumberland CCG
John Ross (JR)	Patient Representative	
Wendy Ross	GP and APC Representative	NHSNewcastle North & East CCG
Helen Seymour	Senior Medicines Optimisation Pharmacist	NECS
Janette Stephenson	Head of Medicines Optimisation	NECS
Simon Thomas	Consultant Clinical Pharmacologist	NUTH
Susan Turner (STu) (Professional Secretary)	Medicines Optimisation Pharmacist	NECS
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Anne-Marie Bailey	Senior Medicines Optimisation Pharmacist	NECS
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Alexander Dyker	Consultant Physician	NUTH
Sue Gordon (SG)	Consultant in Public Health	NHS England
Janet Kelly	Chief Matron for Community Services	NHCT
Tamsin Oswald (TO)	Consultant Microbiologist	NHCT
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Steve Williamson	Consultant Pharmacist in Cancer Services	NHCT/NHSE

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

2014/01 Declarations of interest
No relevant declarations made.

Appeals Nalmefene.

2014/02 Nalmefene use was considered and rejected in Nov 13. An appeal against this decision was lodged with the APC within the required timescale but it has now been agreed that this will be considered by the newly formed Regional group (N-TAG) in February. The applicant has been informed.

2014/03 Minutes and decision summary from the meeting held on Tuesday 12th November 2013.
These were accepted as a true record.

2014/04 Matters arising.
All matters arising were covered by the agenda and action log.

2014/05 Action Log
The action log was reviewed and will be updated to reflect the following progress:

- Newer Oral Anticoagulants – work on the local patient decision aid and Anticoagulant card was previously put on hold as the committee were informed that this work was being picked up nationally. SD agreed to confirm intentions with NICE in order to inform decisions around local work requirements for a Patient Decision Aid. In terms of Patient information cards there are some industry cards available as well as one published by the European Society of Cardiology. The committee agreed the ESC card would be suitable for use. This is available at http://www.escardio.org/communities/EHRA/publications/novel-oral-anticoagulants-for-atrial-fibrillation/Documents/English-EHRA-NOAC-card-A5.pdf
- Tapentadol –A single information sheet emphasising the formulary position is being produced for attachment to clinic letters. ML is progressing this with clinicians.
- Lisdexamfetamine shared care guideline – ML is working with the applicant to ensure completion of this and it will be progressed through the MGUG. Primary care should not be seeing requests for this yet.
- Linaclotide blue information sheet – this is going to MGUG on 15/1/14 for consideration.
- Medical administration Aids Support Tool – ML agreed to circulate this to members.

2014/06 Report from the Formulary Sub-committee
Formulary version 4.7 is now available on the APC website.

Minutes and recommendations from the meeting held on 17th December 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:

Desogestrel 75microgram (Cerelle®) combined oral contraceptive
A branded generic version of desogestrel 75microgram tablets is now available which will lead to cost savings across North of Tyne if used instead of Cerazette®.
The draft Branded vs Generic document presented for approval states that

preferred brands should be included in the formulary. The committee felt this should be amended to state that where patients are initially prescribed desogestrel by brand, then this brand should be continued. The formulary entry would just be for generic desogestrel.

Decision: An umbrella statement will be added to the formulary that will allow branded generics to be used, in accordance with APC guidance, without them being formally listed.

Ibuprofen gel 5%

Ibuprofen gel has been requested to be added to the formulary as there is little difference in efficacy with piroxicam and it is available at reduced cost.

Decision: The request for ibuprofen gel was approved and piroxicam gel will be removed from formulary.

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. It has now been highlighted that although no longer appropriate in treatment of patients with alcohol misuse there is still a potential role in refeeding syndrome. A decision was deferred to seek clarity on this.

Decision: Deferred

LDM Summary Template

Since 1/4/2013 CCGs are the commissioners of many health services in their local area and decisions regarding funding for drugs, which do not fall under the remit of other commissioners of health services (e.g. NHS England, Local Authorities), now rests with them.

NICE recently published good practice guidance on developing and updating local formularies and this guidance recommends that decision making bodies define and consistently apply standard criteria for decision making. It was recognised that the current APC/FSC processes address the majority of the issues raised in the GPG but for governance purposes CCGs need to ensure this process is fully documented.

A draft decision making summary document was presented to the committee for consideration. The aim of this document is to articulate the decision making process that the formulary subcommittee goes through when coming to a decision about a drug application. The form further acts as a means of alerting CCGs to any commissioning implications the inclusion of a drug on the formulary may have (e.g. financial risk, requirement to commission pathways to implement use of drug etc).

The intention is that the form is partly completed following decision making at the formulary subcommittee. CCGs representatives (NECS MO/prescribing leads) will ensure that completion of the Pathway/Commissioning implications box is completed prior to APC and circulated to members and in so doing would prevent any unacceptable delay occurring as a consequence of this proposed change.

The form will be used to inform any internal governance process about the drug application within CCGs and to enable CCG members of the APC to highlight to the committee any potential barriers to implementation of FSC recommendations.

There was a full and frank discussion of the benefits and drawbacks of this new process and it was agreed that CCGs would take responsibility for trialling its use

at the next FSC meeting.

2014/07 Report from the Medicines Guidelines and Use Group

Minutes from the meeting of 6/11/13 were accepted and the following actions taken:

Guidelines for approval:

- APC Guideline on Medicines that are not suitable for generic prescribing – approved subject to a slight amendment under oral progesterone contraceptives as outlined in 2014/06
- Blood Glucose Monitoring – approved subject to inclusion of a statement regarding the importance of reminding patients to use control solutions/calibrate machines in line with manufacturer recommendations.
- Third Party Ordering – deferred. Some concern was expressed regarding the practical implications of adopting this guidance. The principles behind it were agreed but the methodology needs more thought. The document will go back to MGUG for refinement before approval.
- North of Tyne and Gateshead guidelines for management of common urological conditions in adults ≥ 18 years – approved subject to agreement with the author that dates can be changed to Jan 2014 with a 2 year approval.

Information leaflets for primary care for approval:

- Chorionic gonadotrophin - approved
- Dexamfetamine for primary sleep disorders - approved
- Humulin R U500 insulin (500units/ml) – approved although noted that this is still a RED drug.
- Lidocaine Patches - approved
- Mexiletine - approved
- Antipsychotics in psychosis, bipolar disorder and augmentation therapy in treatment resistant depression - approved
- Pramipexole - approved
- Rasagiline - approved
- Ropinirole -approved
- Rotigotine -approved

Shared Care Guidelines

- Immunosuppressive treatment following Heart and/or Lung Transplantation in Adults - approved
- Immunosuppressive treatment following Liver Transplantation in Adults - approved
- Immunosuppressive treatment following Renal Transplantation in Adults - approved
- Lithium -approved
- Atomoxetine in the Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in Children and Young People -approved

Interim Guideline for Clinical Governance

- Immunosuppressive treatment for paediatric nephrotic syndrome – accepted in principle but minor changes needed and therefore this is going back to MGUG on 15/1/14

Assessment Tool

- Risk assessment for clostridium difficile infection – minor changes still needed before approval.

The group decided the following guidelines are no longer needed:

- Spironolactone and Chlorothiazide Capsules
- Eslicarbazepine

- Ibandronic acid
- Ivabradine
- Prucalopride
- Cabergoline
- Rosuvastatin – corrected following meeting. An update will now be undertaken

It was highlighted from the minutes that cinacalcet was now recommended as a RED drug for all indications. This was challenged by the committee as use in primary hyperparathyroidism had previously been approved as suitable for shared care prescribing and clinically this was felt to still be appropriate. The decision was taken that this drug would remain as amber for this indication.

2014/08 Report from the Anti-microbial Chemotherapy subcommittee.

No report due.

2014/09 Documents previously circulated by e-mail

- Email regarding the formation of a new Regional Decision Making Group

The formation of a regional decision making group (N-TAG) was noted. Membership includes representation from organisations served by the APC. Terms of Reference still need finalized and clarification of criteria for products that will be considered is essential in order to reduce duplication of work. JS agreed to check the membership for appropriate CCG representation.

2014/10 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 November and December

- TA298:Choroidal neovascularisation (pathological myopia) - ranibizumab
- TA299:Leukaemia (chronic myeloid) – bosutinib – negative appraisal
- TA300:Hepatitis C (children and young people) - peginterferon alfa and ribavirin
- TA301:Diabetic macular oedema - fluocinolone acetonide intravitreal implant (rapid review of TA271)
- TA302: Juvenile idiopathic arthritis (systemic) - canakinumab (terminated appraisal)

2014/11 NHS England Specialised Services Approval

The following NHS England Specialised Service Approval was noted:

- Aztreonam lysine (nebulised)

The recommendations within it were noted by the committee and the North of Tyne Formulary will be updated to reflect this decision.

2014/12 Chair's action

The previous North of Tyne statement on prescribing of generic epilepsy medications has been removed from website following updated MHRA advice.

2014/13 Any other business

Strontium – MG highlighted that the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended that Protelos/Osseor should no longer be used to treat osteoporosis. The PRAC concluded that the risk/benefit balance was no longer favourable and recommended Protelos/Osseor be suspended until there are new data showing a favourable balance in a defined patient group.

The PRAC recommendation will now be sent to the Agency's Committee for Medicinal Products for Human Use (CHMP), which is expected to issue the Agency's final opinion at its meeting of 20 to 23 January 2014.

It was noted that prescribers will need advice relating to existing patients.

The chairman closed the meeting by thanking everyone for their continued support throughout this period of changing structures.

2014/14 Date and time of next meeting

Tuesday 11th March 2014 at 12:30pm
Room 3, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.

Signed: ..... **Date:** 11/3/14
(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 14th January 2014.**

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				
None				
2) New Requests				
Granisetron 3.1mg/24 hours transdermal patches (Sancuso®)			✓	Granisetron patches have been requested for use in patients to prevent chemotherapy induced nausea and vomiting in multi-day chemotherapy regimens to replace palonosetron capsules. It was indicated that this item could be discussed at the next cancer network clinical group meeting. **Decision:** The request for granisetron patches was deferred until the matter is discussed at the next cancer network clinical group meeting in February 2014.
Azarga® eye drops (brinzolamide 1% / timolol 0.5%)		✓		Azarga® has been requested for the treatment of intra-ocular pressure in patients with open-angle glaucoma or ocular hypertension. It was intended that this would replace Cosopt® eye drops. It was noted that this would lead to significant cost pressures in primary care as generic versions of Cosopt® are used in the majority of patients. Whilst the adverse effects of Azarga® are favourable compared to Cosopt®, the additional cost made a switch extremely prohibitive **Decision:** The request for Azarga® should be rejected on the grounds that there are more cost effective options available on the formulary for use in this cohort of patients.
3) New formulations & extensions to use				
Rifaximin 550mg Tablets (Targaxan®)			✓ See notes	Rifaximin 550mg tablets have recently been licensed for the prophylaxis of hepatic encephalopathy. This preparation is cheaper than the "off label" use of the 200mg tablets. It was considered appropriate to change the status from red to blue to allow for care to be transferred to GP's once patients had been stabilised. It was however noted that NICE are currently reviewing rifaximin for this indication. **Decision:** The request for rifaximin 550mg tablets was approved but the status change from red to blue to allow for prescribing in primary care will be reviewed once the outcome of guidance from NICE is known.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Ciclosporin eye drops 0.06%	✓ R			Ciclosporin eye drops (0.06%) have been requested for use in patients with keratoconjunctivitis for patients who cannot tolerate the 0.2% eye ointment. **Decision:** The request for ciclosporin 0.06% eye drops should be approved subject to it being a red drug. The 2% eye drops will be removed from the formulary.
Calcium Acetate 667mg capsules (PhosLo®)	✓			PhosLo® has been requested for the prevention and treatment of hyperphosphataemia in dialysis patients. Patients have reported difficulty in swallowing Phosex® (calcium acetate 1g tablets) due to the tablets being uncoated and having an unpalatable smell, leading to poor compliance. PhosLo® is a calcium acetate tablet contained within a gelatin capsule. These are cost neutral compared to Phosex®. **Decision:** The request for PhosLo® was approved subject to it remaining cost neutral compared to Phosex®.
4) Products considered by NESCG and decisions endorsed by APC				
Aztreonam lysine (nebulised)	✓ R			**Decision:** Approved in line with NHS England Specialised commissioning criteria.
5) Products considered by NICE				
TA298:Choroidal neovascularisation (pathological myopia) - ranibizumab	✓ R			**Decision:** The formulary will reflect the NICE position.
TA299:Leukaemia (chronic myeloid) – bosutinib – negative appraisal			✓	**Decision:** The formulary will reflect the NICE position.
TA300:Hepatitis C (children and young people) - peginterferon alfa and ribavirin	✓ R			**Decision:** The formulary will reflect the NICE position.
TA301:Diabetic macular oedema - fluocinolone acetonide intravitreal implant (rapid review of TA271)	✓ R			**Decision:** The formulary will reflect the NICE position.
TA302: Juvenile idiopathic arthritis (systemic) - canakinumab (terminated appraisal)				Noted

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
CG172:Myocardial infarction: secondary prevention				Formulary to be updated to reflect that the omega-3 preparations are for hypertriglycerideamia only and no longer for myocardial infarction. Consultation to take place on the continued need of the omega-3 preparations for hypertriglycerideamia.
6) Appeals against earlier decisions by the APC				
Nalmefene (Selincro®) 18mg tablets			✓	Nalmefene use was considered and rejected in Nov 13. It had been requested for use in adult patients with alcohol dependence that have a high drinking risk level without physical withdrawal symptoms who do not require immediate detoxification but who require a reduction of alcohol consumption. The group had concerns over the effectiveness of nalmefene compared to counselling alone and it was felt that the reductions achieved with the addition of nalmefene did not justify the significant additional expenditure. It was also noted that the commissioning for alcohol services is undertaken by local authority public health. An appeal was lodged with the APC within the required timescale but it has now been agreed that this will be considered by the newly formed Regional group (NTAG) in February rather than locally.
7) Miscellaneous decisions by the APC				
Desogestrel 75microgram (Cerelle®) combined oral contraceptive	✓			A branded generic version of desogestrel 75microgram tablets is now available which will lead to cost savings across North of Tyne if used instead of Cerazette®. **Decision:** An umbrella statement will be added to the formulary that will allow branded generics to be used, in accordance with APC guidance, without them being formally listed.
Proxymetacaine 0.5% and fluorescein 0.25% Combined Minims®	✓			This product has been discontinued by the manufacturer. It has been requested that lidocaine 4% and fluorescein 0.25% Minims® be used a replacement. **Decision:** The request for lidocaine 4% and fluorescein 0.25% Minims® was approved.
Ibuprofen gel 5%	✓			Ibuprofen gel has been requested to be added to the formulary as there is little difference in efficacy with piroxicam and it is slightly cheaper. **Decision:** The request for ibuprofen gel was approved and piroxicam gel will be removed from formulary.
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. It has now been highlighted that there is still a potential role in refeeding syndrome. A decision was deferred to seek clarity on this.