North of Tyne
Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 13th May 2014 at Northumbria House, Cobalt Business Park, North Tyneside

Present:

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
Alexander Dyker	Consultant Physician	NUTH
Matt Grove	Consultant Rheumatologist and Head of Service	NHCT
David Jones	GP and APC Representative	NHS Newcastle West CCG
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
Wendy Ross	GP and APC Representative	NHSNewcastle North & East CCG
Helen Seymour	Senior Medicines Optimisation Pharmacist	NECS
Simon Thomas	Consultant Clinical Pharmacologist	NUTH
Sarah Tulip(deputising for AMB)	Medicines Optimisation Pharmacist	NECS
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

Anne-Marie Bailey	Senior Medicines Optimisation Pharmacist	NECS
Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
Russell Buglass	Community Pharmacist	NoT LPC
Sue Gordon (SG)	Consultant in Public Health	NHS England
Tamsin Oswald (TO)	Consultant Microbiologist	NHCT
John Ross (JR)	Patient Representative	

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

2014/30 Declarations of interest

None

2014/31 Appeals

No appeals.

2014/32 Minutes and decision summary from the meeting held on Tuesday 11th March 2014.

These were accepted as a true record.

2014/33 Matters arising not on the agenda.

None

2014/34 Action Log

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

- Tapentadol – presented today for consideration (see 2014/). Remove from action log.
- Lisdexamfetamine shared care guideline – presented today for consideration (see 2014/). Remove from action log.
- Linaclotide blue information sheet – due to go to MGUG for approval 21/5/14 (see 2014/22).
- Letter from Newcastle and Gateshead Alliance (2014/24) – DC informed the committee that he had responded to Mr Piercy as agreed at the March meeting. The Newer Oral anticoagulants comparison chart has been updated following comments and is now available on the website. Remove from action log.
- Domperidone use as a galactagogue (2014/280) – the RDTC are pulling together some Medicines Information resources relating to the recent safety alert and this will be available by the end of the month. The formulary will be annotated in line with the MHRA advice.

2014/35 Annual Report

The report was approved by the committee and will be circulated to the chief executives of member organisations.

The committee wished to note the amount of work undertaken by the subcommittees and thank them for their ongoing support.

2014/36 Report from the Formulary Sub-committee

Formulary version 5.2 is now available on the APC website.

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

Minutes and recommendations from the meeting held on 15th April 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:

Liquid Paraffin Ointment with Vitamin A (VitA-POS®)

VitA-POS® is a vitamin A containing eye ointment requested for the treatment of dry eyes. It is cheaper than current formulary alternatives and is sterile for 6 months from opening.

The FSC recommended that the request for VitA-POS should be approved but on the condition it replaced Duo-lube on the formulary. Following this provisional recommendation it has become apparent that VitA-POS® contains wool fat and therefore Duolube should be retained for patients where there is a documented wool fat allergy.

Decision:Approved
VitA-POS was approved for use. VitA-POS® contains wool fat and therefore Duolube should be retained for patients where there is a documented wool fat allergy.

Relvar
Relvar Elipta® is an inhaled corticosteroid (ICS) and long acting beta agonist combination (LABA) inhaler licensed for Asthma (both strengths) and COPD (92/22 only). It has been requested for both indications on the grounds of lower cost and similar efficacy when compared with existing products. Concerns have been raised nationally that the blue colour of the device could cause patients to mistake this for a "reliever" inhaler and the 92 mcg dose of fluticasone furoate is equivalent to high dose ICS i.e. step 4 in the BTS asthma guidelines, potentially leading to "over dosing".

Decision: Refused
The issue of the livery, and subsequent concerns regarding the potential for patient confusion with blue "reliever" inhalers, have now been raised with the MHRA. The committee has therefore refused the request until GSK act on the nationally raised concerns.

NICE CG171: Urinary incontinence in women
At the March meeting it was agreed as an interim measure that oxybutinin immediate release (IR) and tolterodine IR would now become the 2 agreed first line formulary choices but the FSC was 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 presented by the urology specialists.

It has now been agreed that there is a need for a pathway design that could streamline care. In the meantime, the status quo should be maintained with regards to the formulary choice of antimuscarinic agents with oxybutinin and tolterodine immediate release preparations remaining the first line choices until the review is complete.

Dihydrocodeine
Dihydrocodeine has been requested as a replacement for codeine in adult women post caesarean section who are breastfeeding. There is theoretically the same risk in fast metabolisers with dihydrocodeine as with codeine, therefore more information is required before a decision can be made. The chair indicated that in order to prevent undue delay he would be prepared to take chair's action if consensus on a suitable alternative to codeine can be reached before the next meeting.

Decision: Deferred
Further information is required before dihydrocodeine can be added to the formulary as an alternative to codeine in breast feeding women post caesarean section.

New product application form
The updated product application form was presented for information following changes to reflect previous discussions. This was approved but a request was made to incorporate a "plain language section" that could be used to help lay members on either the FSC or APC understand the rationale behind any

application. This was also supported.
Amended appraisal document – for information and assurance around LDM processes.

2014/37 Report from the Medicines Guidelines and Use Group

Minutes from the meeting of 19/3/14 were accepted and the following actions taken:

Guidelines for approval:

- Branded vs generic update - this has been amended to include reference to midazolam – approved.
- Blood glucose – this has been amended to include reference to urine testing - approved.
- Third Party Ordering – approved subject to minor amendments outlining that this is guidance that may be used where there may be concerns with third party ordering. The guidance can also relate to community pharmacy third party ordering.
- Peripheral Arterial Disease – approved.
- Guidelines for the management of common urological conditions in adults ≥ 18 years – a concern was expressed that many patients would not receive first line drugs if this guidance was followed. The guideline was approved subject to review following the pathway review meeting outlined in 2014/36. The erectile dysfunction guidelines, once finalised, should also be incorporated into this. DC noted that this guideline applied to North of Tyne and Gateshead and pointed out that the committee currently does not have membership from Gateshead CCG.

Information leaflets for primary care for approval :

- Tapentadol - Information for Treatment of Adults in Primary Care – approved.

Shared Care Guidelines :

- Immunosuppression for children with nephrotic syndrome - approved
- Ketamine in Palliative care(cancer pain) -update - approved
- Lisdexamfetamine in the Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children and young people – Approved subject to minor changes relating to third line use.

2014/38 Report from the Anti-microbial Chemotherapy subcommittee.

No report due.

2014/39 Documents previously circulated by e-mail

None

2014/40 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.

- TA307 - Colorectal cancer (metastatic) - aflibercept - negative appraisal
- TA308 - Vasculitis (anti-neutrophil cytoplasmic antibody-associated) - rituximab (with glucocorticoids)
- TA309 Lung cancer (non small cell, non squamous) - pemetrexed
- TA310 Lung cancer (non small cell, EGFR mutation positive) - afatinib
- TA311 Multiple myeloma - bortezomib (induction therapy)

2014/41 Northern (NHS) Treatment Advisory Group (N-TAG)

The following recommendations were noted and the North of Tyne Formulary will

be updated to reflect these decisions:

- Decision Summary Notice - Sequential pharmacological therapies in the management of macular oedema secondary to retinal vein occlusion
- Decision Summary Notice - Nalmefene (Selincro®) in the management of alcohol dependence

N-TAG are finalising their TORs and work plan and these will then be circulated to local decision making groups. In June they are due to consider Rivaroxaban in ACS, dapoxetine for premature ejaculation and Vitamin supplements for macular degeneration.

2014/42 NHS England Specialised Services Approval

The following NHS England Specialised Service Approvals were noted:

- SSC1415: Cystic fibrosis prescribing
- SSC1417: Gender dysphoria
- SSC1419: Sofosbuvir for Hepatitis C
- SSC 1421: NICE TA310: Afatinib
- SSC 1422: NICE TA 308 - ANCA / Rituximab
- SSC 1423: Multiple myeloma bortezomib (induction therapy)

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

2014/43 Chair's action

An update to the North of Tyne Comparison of Newer Oral anticoagulants was approved following appropriate consultation.

2014/44 Any other business

An NTW document on the current clomipramine shortages was circulated to members. An additional section of the APC website will be created for resources that the APC has not produced but acknowledges may be useful to prescribers.

DC reported a discussion he had had with John Ross that morning. JR had indicated that he would be stepping down from the committee and had wished to feedback some of the challenges associated with being a lay member of the APC – this primarily being because of the often technical nature of the discussions. The committee discussed and agreed two proposals that might help in the future; firstly revision to new product application form (see above); secondly providing free access to lay members to any of the APC's subgroup meetings. The committee wished to acknowledge how valuable John's contribution had been to the APC and to thank him for the commitment he had shown since joining the group. HS agreed to explore how we could recruit a new lay member for the group.

2014/45 Date and time of next meeting

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

Signed: ..... **Date:** 8/7/14

(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 13th May 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				
NICE CG171: Urinary incontinence in women				Following the March 2014 APC meeting the FSC was 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 presented by the urology specialists. It has now been agreed that there is a need for a pathway design that could streamline care. In the meantime, the status quo should be maintained with regards to the formulary choice of antimuscarinic agents with oxybutinin and tolterodine immediate release preparations remaining the first line choices until the review is complete.
2) New Requests				
Renavit® multi-vitamins	✓			Renavit® is a water-soluble vitamin supplement for maintenance haemodialysis patients. It is a once daily preparation and is cheaper than current treatment options. Use has been requested in line with current EBPG guidelines for water soluble vitamin supplementation. **Decision: Approved.** The request for Renavit® was approved for use in this cohort of patients.
Lubiprostone (Amitiza®) 24 microgram soft capsules		✓		Lubiprostone is licensed for the treatment of chronic idiopathic constipation in adults when response to diet and other non-pharmacological measures are unsuccessful. Approval was sought for 3rd line use after the failure of other pharmaceutical interventions. **Decision: Refused** There is no evidence of long term benefit and or evidence to support 3rd line use.
Certolizumab (Cimzia®) 200 mg prefilled syringe - Ankylosing spondylitis (AS)		✓		There is some concern over the apparent higher rates of serious infection as suggested in a Cochrane review. The long term cost implications compared to other biologic agents are also unclear. There are already several NICE approved biologic agents for this indication. **Decision: Refused** It was agreed this decision would be reassessed in light of the forthcoming SMC decision.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Certolizumab (Cimzia®) 200 mg prefilled syringe – Psoriatic Arthritis		✓		There is some concern over the apparent higher rates of serious infection as suggested in a Cochrane review. The long term cost implications compared to other biologic agents are also unclear. There are already several NICE approved biologic agents for this indication. **Decision: Refused** It was agreed this decision would be reassessed in light of the forthcoming SMC decision.
Fluticasone furoate 92 mcg & vilanterol 22 mcg inhaler (Relvar Ellipta®) **Fluticasone furoate 184 mcg & Vilanterol 22 mcg inhaler (Relvar Ellipta®)**		✓		Relvar Elipta® is an inhaled corticosteroid (ICS) and long acting beta agonist combination (LABA) inhaler licensed for Asthma (both strengths) and COPD (92/22 only). It had been requested for both indications on the grounds of lower cost and similar efficacy when compared with existing products. Concerns have been raised nationally that the blue colour of the device could cause patients to mistake this for a "reliever" inhaler and the 92 mcg dose of fluticasone furoate is equivalent to high dose ICS i.e. step 4 in the BTS asthma guidelines, potentially leading to "over dosing". **Decision: Refused** The issue of the livery and subsequent concerns regarding the potential for patient confusion with blue "reliever" inhalers have now been raised with the MHRA. The committee have therefore refused the request until GSK act on the nationally raised concerns.
Liquid Paraffin Ointment with Vitamin A (VitA-POS®)	✓			VitA-POS® is a vitamin A containing eye ointment requested for the treatment of dry eyes. It is cheaper than current formulary alternatives and is sterile for 6 months from opening. **Decision: Accepted***:* VitA-POS should be used instead of Duolube unless there has been a documented allergy to wool fat.
3) New formulations & extensions to use				
Fosfomycin 500mg capsules	✓ R			**Decision: Accepted***:* The request for fosfomycin capsules was approved as a hospital only drug for use on microbiology/ID advice following IV courses of fosfomycin for systemic infections. The sachets will continue to be used for treating UTI in both the community and secondary care on the advice of a microbiology specialist and are not classified as RED.
Colecalciferol 800iu tablets (Desunin®)	✓			**Decision: Accepted** Approved for use in patients with vitamin D deficiency. It doesn't contain gelatin, peanut oil, soya or lactose. Cost neutral compared to Fultium-D_3®. The 800unit coleclaciferol preparations are suitable for generic prescribing.
Warfarin 1mg/1ml suspension [s]	✓			**Decision: Accepted** Approved for use in paediatric patients on mechanical support using ventricular assistance devices, and for paediatric patients with mechanical heart valves or irregular heart rhythms who have not yet been weaned and hence are unable to swallow tablets.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC1415: Cystic fibrosis prescribing	noted			The formulary will reflect the NHS England Specialised Services circular position.
SSC1417: Gender dysphoria	noted			The formulary will reflect the NHS England Specialised Services circular position.
SSC1419: Sofosbuvir for Hepatitis C	noted			The formulary will reflect the NHS England Specialised Services circular position.
SSC 1421: NICE TA310: Afatinib	noted			The formulary will reflect the NHS England Specialised Services circular position.
SSC 1422: NICE TA 308 - ANCA / Rituximab	noted			The formulary will reflect the NHS England Specialised Services circular position.
SSC 1423: Multiple myeloma bortezomib (induction therapy)	noted			The formulary will reflect the NHS England Specialised Services circular position.
5) Products considered by NICE				
TA307 - Colorectal cancer (metastatic) - aflibercept - negative appraisal	noted			The formulary will reflect the NICE position
TA308 - Vasculitis (anti-neutrophil cytoplasmic antibody-associated) - rituximab (with glucocorticoids)	noted			The formulary will reflect the NICE position
TA309 Lung cancer (non small cell, non squamous) - pemetrexed	noted			The formulary will reflect the NICE position
TA310 Lung cancer (non small cell, EGFR mutation positive) - afatinib	noted			The formulary will reflect the NICE position
TA311 Multiple myeloma - bortezomib (induction therapy)	noted			The formulary will reflect the NICE position
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
Decision Summary Notice - Sequential pharmacological therapies in the management of macular oedema secondary to retinal vein occlusion	noted			The formulary will reflect the N-TAG position

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Decision Summary Notice - Nalmefene (Selincro®) in the management of alcohol dependence	noted			The formulary will reflect the N-TAG position
7) Appeals against earlier decisions by the APC				
None				
8) Miscellaneous decisions by the APC				
Dihydrocodeine			✔	Dihydrocodeine has been requested as a replacement for codeine in adult women post caesarean section who are breastfeeding. There is theoretically the same risk in fast metabolisers with dihydrocodeine as with codeine, therefore more information is required before a decision can be made. **Decision: Deferred** Further information is required before dihydrocodeine can be added to the formulary as an alternative to codeine in breast feeding women post caesarean section.
MHRA Drug Safety Updates				The formulary will be updated to include the restricted indications and monitoring for strontium ranelate and methysergide.
Pyridoxine injection [u]				This is included in national antidote guidelines for isoniazid toxicity but is not currently on the formulary. It will be added in line with national guidance.
Metformin sachets				Discontinued by manufacturer – to be removed from the formulary.