North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 12th May 2015 at Northumbria House, Cobalt Business Park, North Tyneside

Present:

Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
Pat Bottrill	Lay Representative	
David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Helen Coundon	GP and Prescribing Lead	NHS North Tyneside CCG
Sue Dickinson (SD)	Director of Pharmacy	RDTC
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Alexander Dyker (AD)	Consultant Physician	NUTH
Matt Grove (MG)	Consultant Rheumatologist and Head of Service	NHCT
Steve Llewellyn	Medicines Optimisation Pharmacist	NECS
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Peter McEvedy (PMcE)	GP and Prescribing Lead	NHS Northumberland CCG
Neil Morris	Medical Director	NHS Newcastle Gateshead CCG
Helen Seymour (HS)	Senior Medicines Optimisation Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Simon Thomas (STh)	Consultant Clinical Pharmacologist	NUTH
Susan Turner (STu)	Medicines Optimisation Pharmacist	NECS
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Anne-Marie Bailey (AMB)	Senior Medicines Optimisation Pharmacist	NECS
Russell Buglass(RB)	Community Pharmacist	NoT LPC
Wendy Ross (WR)	GP and APC Representative	NHSNewcastle North & East CCG
Neil Watson(NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Steve Williamson(SW)	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

Dr Neil Morris, Medical Director of NHS Newcastle Gateshead CCG was welcomed to the meeting.

2015/33 Declarations of interest

ML attended an advisory board meeting for Scope Opthalmics.
No other relevant declarations.

2015/34 Appeals against previous decisions

None

2015/35 Minutes and decision summary from the meeting held on Tuesday 12th March 2015

These were accepted as a true record.

2015/36 Matters arising not on the agenda.

None

2015/37 Action Log

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

- Hyaluronic acid injections in osteoarthritis – comments have been received from specialists. The Formulary Subcommittee will review these at its next meeting.
- Ophthalmic preparations review – see 2015/38.
- Inhaler review – see 2015/38
- Neuropathic pain Guideline – approved via Chairs action.

2015/38 Report from the Formulary Sub-committee

Formulary version 5.8 is now available on the APC website.

Minutes and recommendations from the meeting held on 16th April 2015:

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:

Inhaler Review

The recommendations from the recent review were accepted and will be reflected in the formulary.
An aide memoire, outlining formulary choices and giving supporting information for clinicians, was approved. It was agreed that it was not appropriate to undertake inhaler switching programmes without patient involvement. Where devices differed from those currently being used, it was agreed that patients need to be appropriately counselled before any change is made as correct inhaler technique is essential to effective treatment. Inhalers should be prescribed in line with the APC document APC Guideline on Medicines that are Not Suitable for Generic Prescribing-May2014.
Concern was expressed that generic prescribing may result in a change of product at the dispensing stage, without appropriate consultation. The committee agreed that the help of the LPC should be sought in ensuring that appropriate professional support is given to patients when any change in their inhaler is made, including when medication is delivered directly to a patient`s home.

Ophthalmic preparations review

A recent ophthalmic preparation review has been undertaken. The recommendations from that review were accepted and will be reflected in the formulary.

Lipid modification guidelines

NICE clinical guidance 181, Lipid modification, makes recommendations which impact upon the Formulary. These are:

- CoEnzyme Q10: to remain for lipid clinic initiation only in patients with severe hyperlipidaemia who are not tolerating statins due to myopathy.
- Fibric acid analogues: for lipid clinic initiation only in patients with combined hyperlipidaemias and severe hypertriglycerideamia
- Bile acid sequestrants: for lipid clinic initiation only in patients with familial hypercholesterolaemia and /or those with substantial cardiovascular risk and who are unable to tolerate existing treatments. The use of colestyramine for the washout of leflunomide was recognised and it was agreed this should be reflected in the Formulary (red status).
- Nicotinic acid group: to be removed.

2015/39 Report from the Medicines Guidelines and Use Group

Draft minutes from the meeting held on 18/03/15 were received.
The Chair of MGUG has taken chairs action to withhold the COPD Guideline at present. He has received information informing him that CCGs cannot support these in their current form as there are concerns that they are outside of NICE Guidance.
The committee agreed that the guidelines should only come to APC once they have all party agreement. Mr Campbell stated that guideline development groups needed to consider the commissioning framework they are operating within.
The traffic light list has been updated and is available on the website.
The following guideline was submitted for approval :

- Proton Pump Inhibitors (PPIs) – Subject to a minor alteration, to include a specific dose when double dose H2 Receptor antagonists are referred to, this was approved.

The following information leaflets for primary care were submitted for approval

- Denosumab (Prolia®) 60mg sc twice yearly for osteoporosis - Approved
- Memantine: information for primary care - Approved
- Acetylcholinesterase inhibitors: information for primary care - Approved

2015/40 Report from the Anti-microbial Chemotherapy subcommittee.

The antimicrobial chemotherapy sub-committee has not met formally for several months and their remit has changed now that a regional guideline has been adopted in the North of Tyne area. It was agreed that there was continued value in retaining the informal network arrangements that were in place across the North of Tyne area in relation to antimicrobial prescribing but the remit in terms of development of primary care guidelines was now no longer necessary. The committee agreed that the Anti-microbial Chemotherapy subcommittee would cease to exist in a formal capacity and thanked members for their previous contributions.

2015/41 Annual Report

The Annual Report was received and approved.
Members were asked to ensure appropriate circulation to relevant committees/personnel in their organisations.

2015/42 Terms Of Reference

The terms of reference are due for review. Current CCG structures and commissioning arrangements need to be reflected in these, particularly with

regards to the recent merger of Gateshead CCG with the Newcastle CCGs. Members have one week to comment on the document before chairs action will be taken to approve these.

2015/43 North of Tyne Area Prescribing Committee Position Statement on Biosimilars

Previous comments have been reflected in this updated paper. The following recommendations were endorsed:

Recommendations

1 Small molecule biosimilars, e.g. erythropoietin can be treated as generics and chosen on basis of cost and other factors by standard pharmaceutical contracting processes.

2 Larger molecule biosimilars, e.g. Monoclonal antibodies (MABs) should be subject to evaluation of evidence before being commissioned.

3 MAB biosimilars offer potential for significant savings for healthcare commissioners and providers so their introduction is desirable and a case should be made for their introduction.

4 Local Decision makers must ensure an assessment that details a comparison with the biological reference product has been undertaken for biosimilar monoclonal antibodies. This could be by N-TAG, SMC, NICE or an NHS England Clinical Reference Group.

5 The role of the Local Decision makers is to ensure that the license granted by the EMEA for biosimilar MABs has been compared with that of the originator molecule and to undertake due diligence on any differences before adoption to ensure the place in practice is defined.

The APC will not be expected to receive formulary submissions for biosimilar monoclonal antibodies and will liaise with N-TAG as appropriate.

2015/44 NICE Technology Appraisals

The following Technology Appraisals were noted and the recommendations within them will be reflected in the formulary:

- TA335 Rivaroxaban for preventing adverse outcomes after acute management of acute coronary syndrome
- TA336 Empagliflozin in combination therapy for treating type 2 diabetes
- TA337: Rifaximin for preventing episodes of overt hepatic encephalopathy
- TA338 Pomalidomide for relapsed and refractory multiple myeloma previously treated with lenalidomide and bortezomib - negative appraisal

2015/45 Northern (NHS) Treatment Advisory Group (N-TAG)

The following papers and recommendations were noted and will be reflected in the formulary :

- Aripiprazole long acting injection (Abilify Maintena®) for schizophrenia
- Paliperidone long-acting injection (Xeplion®) for schizophrenia
- Lurasidone (Latuda®) for the treatment of schizophrenia in adults
- Airsonett® laminar flow device for treatment of uncontrolled allergic asthma
- Rituximab for the treatment of Immune (Idiopathic) Thrombocytopenic Purpura (ITP) in adults and children (unlicensed indication)
- North of England guidance for long acting antipsychotic injections

A question was raised in relation to the traffic light status of antipsychotic agents in schizophrenia and a statement will be added to the formulary to note that this will be reviewed to ensure it is in line with current NICE Guidance.

2015/46 **NHS England**

The following NHS England communications were noted:

- SSC 1507 Early Access to Medicines Scheme – Pembrolizumab for metastatic melanoma
- SSC 1508 NICE Technology Appraisal 333: Axitinib for treating advanced renal cell carcinoma after failure of prior systemic treatment
- SSC 1510 Cancer Drug Fund: National CDF Cohort list
- SSC 1511 Clinical Commissioning Policy: Dolutegravir for treatment of HIV-1 in adults and adolescentsNHS England Clinical Commissioning Policy:
- SSC 1512 Clinical Commissioning Policy:Use of Plerixafor for Stem Cell Mobilisation (Update)
- SSC 1513 Clinical Commissioning Policy: Use of defibrotide in severe veno-occlusive disease following stem cell transplant
- SSC 1514 Clinical Commissioning Policy: Haematopoietic Stem Cell Transplantation (HSCT) (All Ages): Revised.
- SSC 1515 Commissioning Hepatitis C Operational Delivery Networks
- SSC 1516 Pre-Exposure Prophylaxis (PrEP) to prevent HIV: clarification of commissioning position
- SSC1517 Cancer Drug Fund: Notification of Discounts and Rebates

2015/47 **Documents previously circulated by e-mail**

2015/48 **Chair's action**

The following guidance has been approved:

- Analgesic guideline for non-malignant pain.
  - PIL for gabapentin slow dose increase
  - PIL for gabapentin fast dose increase
  - PIL for pregabalin slow dose increase
  - PIL for pregabalin fast dose increase
- Updated NOAC comparison document

2015/49 **North of England Strategic Clinical Networks**

A NOAC Alert card from North of England Strategic Clinical Network was noted.

2015/50 **Any other business**

None

2015/51 **Date and time of next meeting**

The business of the APC and FSC has reduced following the formation of N – TAG. It was agreed that from July the meetings would take place on a quarterly basis. This will be subject to ongoing review.

Tuesday 14th July 2015 at 12:30pm

Room 4, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.

Signed: ..... **Date:** 29/7/15

(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 May 2015.**

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				
No new deferrals				
2) New Requests				
Estradiol 0.06% Topical Gel (Oestrogel®)	✓ B u			Estradiol 0.06% Topical Gel (Oestrogel®) has been requested as a feminising hormone for use in gender dysphoria therapy. This is an unlicensed indication. Evidence of efficacy is limited but it is regarded as non-inferior to the current formulary preparation. Monitoring will be undertaken to determine sufficient absorption. **Decision:** The request for estradiol 0.06% topical Gel (Oestrogel®) was approved.
Calcium acetate 475mg and 950mg tablets (Renacet®)	✓ s			Calcium acetate 475mg and 950mg tablets (Renacet®) have been requested due to the recent discontinuation of PhosLo®. They will initially be used as the second choice calcium acetate preparation for the treatment of hyperphosphatemia associated with chronic renal insufficiency in patients undergoing dialysis. **Decision:** The request for calcium acetate 475mg and 950mg tablets (Renacet®) was approved.
3) **New Formulations & Extensions to Use**				
Ursodeoxycholic acid 500mg tablets (Ursofalk®)	✓ s			Ursodeoxycholic acid 500mg tablets (Ursofalk®) have been requested in addition to 150mg tablets and 250mg capsules. This is anticipated to reduce the pill burden for some patients and has lower acquisition costs. **Decision:** The request for Ursofalk® was approved.
Rivastigmine patch 13.3mg (Exelon®)	✓ B			Rivastigmine patch 13.3mg (Exelon®) has been requested by NTW for use in patients who require a higher dosage than 9.5mg. Currently 9.5mg and 3.6mg patches and used together to create the higher dosage which is more costly. **Decision:** The request for rivastigmine patch 13.3mg (Exelon®) was approved.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC 1507 Early Access to Medicines Scheme – Pembrolizumab for metastatic melanoma				NHS England position noted
SSC 1508 NICE Technology Appraisal 333: Axitinib for treating advanced renal cell carcinoma after failure of prior systemic treatment				NHS England position noted
SSC 1510 Cancer Drug Fund: National CDF Cohort list				NHS England position noted
SSC 1511 Clinical Commissioning Policy: Dolutegravir for treatment of HIV-1 in adults and adolescents NHS England Clinical Commissioning Policy.				NHS England position noted
SSC 1512 Clinical Commissioning Policy:Use of Plerixafor for Stem Cell Mobilisation (Update)				NHS England position noted
SSC 1513 Clinical Commissioning Policy: Use of defibrotide in severe veno-occlusive disease following stem cell transplant				NHS England position noted
SSC 1514 Clinical Commissioning Policy: Haematopoietic Stem Cell Transplantation (HSCT) (All Ages): Revised.				NHS England position noted
SSC 1515 Commissioning Hepatitis C Operational Delivery Networks				NHS England position noted
SSC 1516 Pre-Exposure Prophylaxis (PrEP) to prevent HIV: clarification of commissioning position				NHS England position noted

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
SSC1517 Cancer Drug Fund: Notification of Discounts and Rebates				NHS England position noted
5) Products considered by NICE				
TA335 Rivaroxaban for preventing adverse outcomes after acute management of acute coronary syndrome				The formulary will reflect the TAG.
TA336 Empagliflozin in combination therapy for treating type 2 diabetes				The formulary will reflect the TAG.
TA337: Rifaximin for preventing episodes of overt hepatic encephalopathy				The formulary will reflect the TAG. It was agreed that the traffic light status of rifaximin could now change from Red to specialist initiation.
TA338 Pomalidomide for relapsed and refractory multiple myeloma previously treated with lenalidomide and bortezomib - negative appraisal.				The formulary will reflect the TAG.
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
Aripiprazole long acting injection (Abilify Maintena®) for schizophrenia				The formulary will reflect the N-TAG recommendation.
Paliperidone long-acting injection (Xeplion®) for schizophrenia				The formulary will reflect the N-TAG recommendation.
Lurasidone (Latuda®) for the treatment of schizophrenia in adults				The formulary will reflect the N-TAG recommendation.
Airsonett® laminar flow device for treatment of uncontrolled allergic asthma				Noted

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Rituximab for the treatment of Immune (Idiopathic) Thrombocytopenic Purpura (ITP) in adults and children (unlicensed indication)				The formulary will reflect the N-TAG recommendation.
7) Appeals against earlier decisions by the APC				
None				
8) Miscellaneous decisions by the APC				
Inhaler review	Following a recent review meeting the following decisions will be reflected in the formulary: <u>COPD</u> LAMA •Tiotropium and aclidinium should remain as the first choice LAMAs. •Glycopyrronium should be removed from formulary. LABA/LAMA •Duaklir Genuair® should be added to the formulary (first choice). •Anoro Ellipta® should be added to the formulary (second choice). •Ulitbro Breezhaler® should be added to the formulary (for patients unable to tolerate/use the first and second line choices). LABA/ICS •It was agreed that the Seretide Evohaler® should be removed from the formulary for COPD. •DuoResp® to be added as the first choice budesonide/formoterol preparation. •Relvar Ellipta® 92/22 to be added to the formulary. <u>Asthma</u> •Both DuoResp® and Symbicort® will be made available with DuoResp® being first choice . •Relvar Ellipta® 92/22 and 184/22 should be added to the formulary. The formulary will contain a warning that these are equivalent to high dose ICS and are not suitable for those who may be suitable for stepping down •Flutiform® has a role for patients who wish to continue using PMDI + a spacer and is a cheaper alternative to the Seretide® PMDI. •Tiotropium Respimat® should be added to the formulary for use at Step 4 of BTS/SIGN guidelines. The formulary will state that treatment should be stopped if not effective.			

Product	Decision Approved | Refused | Deferred	Comments/notes
Ophthalmic preparation review	An ophthalmic preparation review to look at the cost effectiveness of prescribing eye drops, in particular unlicensed products, was recently undertaken with the following recommendations now endorsed: • Hypromellose 0.3%w/v PF - remove the unlicensed product from formulary and replace with Tear-Lac® first line and PF Drops® second line. • White soft paraffin/ lubricants - remove specialist initiation from Vita-POS®. Leave Duolube® as specialist initiation – remove Lacri-lube. • Unlicensed chloramphenicol 0.5% preservative free drops – replace with Minims unit dose vial (UDV) as first choice, with the unlicensed multi-dose preparation being kept for patients unable to use the Minims due to dexterity problems. • Cosopt® - remove brand from formulary and keep generic description. • Unlicensed dexamethasone 0.1% preservative free drops - replace with Minims UDV as first choice, with the unlicensed multidose preparation being kept for patients unable to use the Minims due to dexterity problems. • Ganfort® - remove brand from formulary but keep generic description. • Carmellose sodium 0.5 &1% 0.4ml unit dose eye drops – remove the UDVs and replace with PF Drops® • Sodium hyaluronate - add Hylo-Tear® and Hylo-Forte® . Keep Clinitas® 0.4% UDVs for use on specialist recommendation. Xalacom® - remove brand from formulary but keep generic description. • Unlicensed Sodium chloride 5% preservative free - replace with PF Drops® sodium chloride 5%.	
Lipid Modification	NICE clinical guidance 181, Lipid modification, makes recommendations which impact upon the Formulary. The Formulary Subcommittee discussed the suggested changes in conjunction with feedback from specialists. The following recommendations were agreed: •CoEnzyme Q10: to remain for lipid clinic initiation only in patients with severe hyperlipidaemia who are not tolerating statins due to myopathy. •Fibric acid analogues: for lipid clinic initiation only in patients with combined hyperlipidaemias and severe hypertriglycerideamia •Bile acid sequestrants: for lipid clinic initiation only in patients with familial hypercholesterolaemia and /or those with substantial cardiovascular risk and who are unable to tolerate existing treatments. The use of colestyramine for the washout of leflunomide was recognised and it was agreed this should be reflected in the Formulary (red status). •Nicotinic acid group: to be removed.	
Tiotropium	The TIOSPIR trial has demonstrated that the cardiac safety of tiotropium is similar via the Respimat® or Handihaler® devices. The Formulary previously stated that the tiotropium Respimat® should only be used in patients unable to use the Handihaler®. This statement can now be removed, giving both devices equal footing.	