North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 8th March 2011 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
David Cook (DCo) (Professional Secretary)	Lead Clinical Pharmacist, Procurement and Formulary	NHCT
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Rosie England (RE)	Associate Director of Medicines Management	NHS NoT
Sue Gordon (SG)	Executive Director of Public Health	NHS NoT
Matt Grove (MGr)	Consultant Rheumatologist, NTGH	NHCT
Zahra Irannejad (ZI)	Head of Prescribing	NNTCH
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Peter McEvedy (PM)	GP representative from the PBC community North of Tyne	NHS NoT
Simon Thomas (ST)	Consultant Clinical Pharmacologist	NUTH
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NECN
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

In Attendance

David Spencer (DS) (for item 2011/16)	Consultant in Respiratory Paediatrics, Great North Children's Hospital	NUTH

Apologies

Sue Brent	Director of Pharmacy	RDTC
Alexander Dyker	Consultant Physician	NUTH
Mike Guy	Medical Director	NHS NoT
Janet Kelly	Nurse Clinical Manager	NNTCH
Tom McCullough	Community Pharmacist	
Alison Smith	Prescribing Adviser (Provider) – representing prison service	NNTCH
Neil Watson	Clinical Director of Pharmacy and Medicines Management	NUTH

NECN	North of England Cancer Network
NHCT	Northumbria Healthcare NHS Foundation Trust
NHS NoT	NHS North of Tyne
NNTCH	Newcastle, North Tyneside Community Health Services
NTWT	Northumberland Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre

2011/14 Minutes of the meeting held on Tuesday 11th January 2011

Under item 2011/05, report from the Shared Care Group (SCG), the minutes of the meeting held on Wednesday 15th September 2010 should read Wednesday 15th ***December*** 2010. Otherwise the minutes were accepted as a true record.

2011/15 Matters arising

2011/08 Non-Formulary requests

Data indicating the use of non-formulary drugs for all organisations was reviewed. Compliance with the Formulary appeared to be much higher in secondary care than in primary care and it was felt that more detailed analysis of the data was needed. RE for commissioners and ZI for providers agreed to work together to examine the data and investigate ways in which Formulary compliance in primary care can be improved. This would be picked up and reported as part of APC business as a result of agreement under item 2011/20.

ACTION: RE and ZI to investigate ways in which Formulary compliance in primary care can be improved.

2011/12a Use of clopidogrel in TIAs

A paper prepared by North of Tyne stroke physicians had been circulated. This proposed that the APC approve the use of clopidogrel for the unlicensed indication (hence not covered by NICE TAG 210) of secondary prevention of vascular events in patients with transient ischaemic attack (TIA). It was agreed that the data and references in the paper would be checked, as is the normal APC process, and approved by Chair's action if no problems were found. If problems were found, then the paper would be sent to the Formulary Sub-committee.

ACTION: SG and RE to check the references and data in the paper and inform DCa. DCa to approve by Chair's action if no problems found or refer to the Formulary Sub-committee if problems were found.

2011/12b Interim guidance on provision of oral nutritional support

No negative comments had been received by the Chair to this document so it had been approved by Chair's action.

2011/12c Guideline on prescribing PPIs

This had not been approved by the Chair as comments had been received regarding clarification around 'high risk groups'. These comments had now been incorporated into the paper so it was approved by the committee.

2011/12d NICE TA 195 – Rheumatoid arthritis

Rheumatologists North of Tyne had discussed this document and the placement of Abatacept in the Formulary.

DECISION: Abatacept was approved for addition to the Formulary for use according to NICE guidelines.

2011/16 Appeals against previous decisions

a) Omalizumab in children aged 6 to 11 years old (removed from Formulary by APC on 11th January 2011)

Dr David Spencer, Consultant in Respiratory Paediatrics, Great North Children's Hospital attended for this item. Dr Spencer, in presenting the appeal, made the following points:

- RCTs showing efficacy of omalizumab were mainly derived from the USA where asthma management is very different and the use of oral and inhaled corticosteroids (OCS and ICS) is less. Also it is targeted at treating moderate asthma.
- The BTS Guidelines of 2008 do not contain a statement around the use of oral steroids and no studies recognise their reduction as an outcome measure.
- In considerations by NICE:
    - There was no study to guide usage in truly severe paediatric asthma

requiring long term oral steroids.
  - The only paediatric study was poor, having only 2% of patients on oral steroids i.e. not severe disease.
  - The cost benefit of long term steroid reduction was not considered
- Admission levels and QALYs, as noted by NICE, were not the best measures for this patient group.
- In local practice, patient work-up is very vigorous and they are only considered for a trial with omalizumab if they are dependent on long term OCS, the reduction of these being considered the most important outcome.

As a result of these points, Dr Spencer felt that omalizumab should be retained in the Formulary for the treatment of severe persistent allergic asthma in children aged 6 to 11 years.

The committee reviewed the data presented and the points raised for the appeal, noting in particular that of the cohort looked at by NICE, only 2% were on oral steroids, which was different from the cohort presented for the appeal i.e. a different group of patients were being treated by Dr Spencer. However the committee was also mindful of going against NICE decisions unless there were exceptional local circumstances. The committee decided that it could not accept the appeal but was very sympathetic to Dr Spencer's use of omalizumab in a group of patients not fully considered by NICE.

DECISION: The appeal was rejected.

2011/17 Report from the Formulary Sub-committee

a) Minutes and recommendations from the meeting held on Tuesday 8th February 2011

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**. However the following specific points were highlighted:

- Golimumab – This was approved for use strictly in accordance with the algorithm produced by MGr (see item 2011/17b) and with explicit patient consent on its use.
- Tacrolimus (Advagraf®) – Clinicians had expressed a desire to make a choice in product, depending on clinical criteria. Information on what the clinical criteria was, had been requested but had not been provided in time for consideration by the committee. As a result the decision was made that Advagraf® be approved for use in patients currently prescribed Prograf® and new patients would be prescribed Adoport®.
- Angiotensin receptor blockers – The Formulary Sub-committee would be reviewing this group of medicines.

b) Algorithm for the use of Golimumab

This was noted and approved for use.

c) Review of Growth Hormones

These products had been reviewed by the Formulary Sub-committee and a paper prepared for the APC. The paper's recommendations had been considered and accepted with minor amendments.

DECISION:

1. Given that there is no evidence of difference in efficacy and safety between the available preparations Omnitrope® should be used in all de novo paediatric patients. Using Omnitrope® in all de novo patients would realise a maximum recurring saving of £18,500 pa. The uptake of Omnitrope® will be

monitored and it is anticipated that it will make up the majority of new prescribing within 12 months.
2. The healthcare professional involved may consider another device is necessary, for example in true needle phobia. Specific criteria should be drawn up to justify the use of the more expensive preparations.
3. Genotropin® MiniQuick will be maintained to ensure availability for patients when travelling.
4. The use of other assay services should be explored to facilitate the use of lower cost rhGH preparations in adult patients.
5. There is an expectation that existing patients, where appropriate, will be switched to the low cost rhGH preparations. This would realise maximum savings of approximately £200,000 pa.

d) Formulary version 2.9 (January 2011)
This version of the Formulary is now available on the APC website.

2011/18 Report from the Shared Care Group (SCG)
No meeting of this group had been held.

a) Information leaflets for primary care
- Denosumab – This was approved and would be placed on the APC website.

2011/19 Report from the Antimicrobial Chemotherapy Sub-Group
No meeting of this sub-group had been held.

2011/20 Quality, Improvement, Productivity and Performance (QIPP)
A paper had been received from NHS North of Tyne proposing that the NHS North of Tyne Medicines Management QIPP Board merge with the North of Tyne APC. Both groups have similar membership and after discussion it was agreed that the QIPP Board should become a sub-group of the APC.
A paper from the QIPP Board was noted, proposing the switching of Venlafaxine MR capsules/tablets to immediate release tablets. This proposal was accepted.

DECISION: The NHS North of Tyne Medicines Management QIPP Board to become a sub-group of the APC.
The QIPP Board paper 'Switching of Venlafaxine MR capsules/tablets to immediate release tablets' was accepted by the APC.

2011/21 Monitored dosage systems (MDS)/compliance aids
DCo reported that within the North Tyneside and Northumberland areas the training of social services staff is continuing (following a policy change) so that they will be able to prompt from original containers rather than just MDS. The plan is that all new patients needing an MDS will be discharged from hospital without one and assessed in the community by a Reablement Team. Following this step for new patients, existing patients with MDS will be assessed with a view to moving them back to original medicine containers. Within the Newcastle area work is also progressing.

ACTION: ZI to check and confirm developments within Newcastle.

2011/22 NPC Diagnostic Tool review
This paper was received and the following points highlighted:
- A framework was needed for monitoring APC decisions and their implementation. However it was recognised that taking on responsibility for medicines related QIPP would provide a useful solution to this problem.

- The need for robust and transparent criteria for decision making. RE agreed to circulate some information which would be discussed at the next meeting with an expectation for approval.

ACTION: RE to circulate information on decision making criteria for consideration/approval at the next meeting.

2011/23 Documents previously circulated
These were noted as having been received.

2011/24 Chair's action
Nothing to report.

2011/25 Any other business

a) APC Website
Problems had come to light regarding the hosting of the APC website. DCo would keep the committee informed of any developments.

b) IV Colloids
The journal 'Anaesthesia and Analgesia' had recently retracted several articles published by Joachim Boldt, a leading advocate for the use of colloids, after serious concerns about the studies undertaken. As some of these studies were included in the evaluation process which led to APC approval of these products, it was felt that the applicants should be approached to see if the retraction of these articles affected their support for these products.

ACTION: DCo to contact the applicants to see if the retraction of these articles affected their support for IV colloids.

c) Durham and Darlington APC
This committee had just been established and there was the possibility of some joint working but this is undefined at this stage.

d) NETAG
A clinician had asked if an application could be considered by the APC for one of the fentanyl products considered by NETAG on 8th October 2009, but for a different indication. As NETAG had made a blanket recommendation that these products should not be used within NHS North East, it was felt that the applicant should contact the NETAG Professional Secretary, Will Horsley for advice.

e) Human Chorionic Gonadotrophin (hCG)
This is classified as a RED drug for use in fertility treatment. However it has been used for many years in the treatment of hypogonadism which is more appropriate as BLUE. The committee agreed to this amendment

DECISION: hCG to be classified as a BLUE drug when used for hypogonadism.
ACTION: ML to arrange for preparation of a primary care information leaflet.

2011/26 Date and time of next meeting
The date of the next meeting is Tuesday 10th May 2011.
Venue: Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park.

Signed: ..... **Date:** 10/5/.....
(Chair of the APC)

APPENDIX 1

North of Tyne
Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 8th March 2011.**

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 = drugs used in Tertiary Care only.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
No requests were deferred from previous meetings.				
2) New Requests				
Abidec® multivitamin drops	√			Requested on the grounds that they contain less vitamin A than Dalivit®, the product currently included in the North of Tyne Formulary, and will therefore reduce the potential adverse effects associated with excess vitamin A. Abidec® would be used as a routine supplement and Dalivit® vitamin drops would be restricted for use in patients who require a full supplement dosage of vitamin A, eg.Cystic Fibrosis. Abidec® is cheaper than Dalivit®. **Decision** - Approved for use in children and adults. Dalivit® drops to be retained for use in patients requiring a full supplement of vitamin A.
Gaviscon® Advance		√		Requested for use in the treatment of the symptoms of laryngopharyngeal reflux (LPR) for the following groups of patients: • Patients on PPIs who still have symptoms of LPR • Patients who are non compliant to PPI therapy or where PPI therapy therapy is contraindicated. • Patients where a step down or step off PPI is required. Gaviscon® Advance suspension has a licensed indication for the symptomatic treatment of LPR, whereas the other alginates do not, and it is also indicated to be used with a PPI and hence can be utilised to manage breakthrough symptoms whilst on PPI therapy and to aid step down/ step off PPI treatment. It has a reduced dosage volume compared to other alginate containing products, and hence may improve patient compliance and thereby increase treatment efficacy. **Decision** - Not approved. The committee was not convinced that Gaviscon® Advance has any therapeutic advantage over the Formulary choice of alginate, Peptic®.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Golimumab	√ R			A new anti TNF-α drug requested for use in patients who satisfy the relevant NICE criteria for use of an anti TNF agent in the treatment of RA, PsA and AS. Golimumab is broadly similar to adalimumab, etanercept and certolizumab in that it is administered s/c by the patient. The main difference being that it is administered monthly. At present due to the access scheme which offers free stock prior to NICE assessment; it is cheaper than alternative treatments. The manufacturers are offering a free supply, for up to 10 patients per indication (RA, PsA and AS) per consultant rheumatologist, until NICE issues a recommendation for each indication. Clinical trials have demonstrated that golimumab is an effective and safe drug to use, but there have been no comparative studies published as yet. NICE are currently appraising the drug. The use of golimumab will result in savings in the start of treatment, and will be slightly more expensive thereafter when compared to adalimumab. **Decision** - Approved for use strictly in accordance with the treatment algorithm produced by the rheumatologists and with explicit patient consent on its use. It should not be prescribed for patients who have failed on all of the options currently available.
Hyperbaric Prilocaine 2% (Priloketal®)	√			A local anaesthetic that has a shorter effect profile to hyperbaric bupivicaine, but has an identical block quality. It has been requested for use in patients undergoing spinal anaesthesia for day surgery where the procedure is anticipated to take no longer than 90 minutes; and in patients undergoing spinal anaesthesia as an in patient where the procedure is anticipated to take no longer than 90 minutes and the persistence of a motor block is detrimental to early mobilisation. It has been requested on the grounds that it has similar efficacy and safety to hyperbaric bupivicaine. Hyperbaric prilocaine is more expensive than the product currently used, but there are potential savings to be made. Discharge home on the day of surgery reduces the costs associated with an overnight stay in hospital. Aged patients with significant co-morbidities are a continuing challenge for anaesthetists and spinal anaesthesia is a popular method of anaesthesia in this patient group. **Decision-** Approved for use in the indications requested.
3) New formulations & extensions to use				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Lithium for cluster headaches	√ R			Requested for use in the treatment of cluster headaches in patients that have failed other treatments. It has been claimed to have a therapeutic advantage over existing treatment. Chronic cluster headache is usually responsive to verapamil, which is first line for most UK physicians. Topiramate is used as an alternative to verapamil. Trial evidence and expert opinion suggests that lithium can be a useful drug in patients who have failed on simpler medications. Lithium is listed in the BNF for this indication, but is unlicensed for it. **Decision** - Approved for use in the treatment of cluster headaches. It is classed as a RED drug for this indication until the Shared Care Working Group has discussed its traffic light classification. The NPSA guideline should be followed including use of a Patient Information Leaflet.
Mesalazine MR tablets (Asacol® MR)		√		Measlazine 800mg MR tablets have been requested for use as a second line treatment for patients with moderate ulcerative colitis that flares, despite 2.4g mesalazine, and it will also be used as an option for patients who have compliance issues due to pill burden. The existing products that are included in the NoT Formulary are not licensed for doses above 2.4g. Trials have shown that the higher dosing of 4.8g daily gives a higher success rate at 6 weeks compared with 2.4g daily. In 2010 a review of mesalazine products was carried out. The two long acting mesalazine products were not approved for inclusion in the Formulary as there was no consensus between the different acute units as to which product was preferable. The gastroenterologists in Newcastle Upon Tyne Hospitals NHS Trust do not feel that there is a strong case for the inclusion of long acting mesalazine products, but consultants at NHCT are in favour of using it. There is also concern that this product will not be restricted to Secondary Care and will result in a considerable increase in cost in Primary Care. **Decision** - Not approved.
Tacrolimus (Advagraf®)	√			Advagraf® is a prolonged release formulation of tacrolimus that is licensed for once daily administration. Advagraf® has an efficacy and safety profile comparable to the widely used immediate release formulation (Prograf®). It has been requested for use for prophylaxis of organ rejection in kidney and liver transplantation. This is on the grounds that it will aid patient compliance and lead to improved outcomes. A branded generic, Adoport®, which is considered bioequivalent to Prograf®, has recently become available as well. There are potential for savings to be made both in Primary Care and Secondary Care from replacing Prograf® with either Advagraf® or Adoport®. **Decision** - Advagraf® approved for use in patients who are currently prescribed Prograf®. *De novo* patients should be prescribed Adoport®.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
4) Products considered by NECDAG				
Bendamustine (Levact®)	√ R			Approved for first line treatment of chronic lymphocytic leukaemia (Binet stage B or C) in patients for whom Fludarabine combination chemotherapy is not appropriate.
Rituximab (MabThera®)				Aproved for first line maintenance in follicular non-Hodgkin's lymphoma.
5) Products considered by NETAG				
Anti-vascular endothelial growth factor (aVEGF) therapies	See notes			aVEGF therapies, bevacizumab and ranibizumab, were considered in the management of macular oedema secondary to retinal vein occlusion. **Decision** - Bevacizumab 1.25mg using a 'when required' (PRN) regimen is recommended for use in NHS North East in the management of macular oedema secondary to retinal vein occlusion. This is considered a more a cost effective treatment option in RVO compared with ranibizumab.
Dabigatran	See notes			NETAG considered the cost impact of the use of dabigatran for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation based on preliminary recommendations from the Cardiac Rhythm Management Group of the North east Cardiovascular Network. **Decision** – Warfarin recommended as remaining the treatment of choice for patients with non-valvular atrial fibrillation and a CHADS-2 score ≥ 2, except for: 1. Patients with specific contra-indications to warfarin, for example those with a bleeding risk defined by a valid bleeding score, important and unavoidable drug interactions, scheduled interventions such as cardioversion, or other accepted criteria. 2. Patients who have failed to demonstrate adequate anticoagulant control based on a threshold of time-in-therapeutic range (TTR) ≥ 50% after a defined period of warfarin therapy. In these circumstances dabigatran is considered a cost-effective treatment option.
Leukapheresis with Adacolumn®		√		NETAG considered the Adacolumn® leukapheresis treatment system withinits approved indication for the treatment of moderate to severe active inflammatory bowel disease. **Decision** – Not recommended for use within NHS North East for the treatment of inflammatory bowel disease.
6) Appeals against earlier decisions by the APC				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Omalizumab in children aged 6-11 years old		See notes		Recent NICE guidance states that omalizumab is **not** recommended for the treatment of severe persistent allergic asthma in children aged 6 to 11 years. Omalizumab for use in children aged 6-11 years was removed from the Formulary by the APC at its meeting on 11th January 2011. However children currently receiving omalizumab for the treatment of severe persistent allergic asthma were allowed the option of continuing treatment until it was considered appropriate to stop. **Decision** – Appeal rejected. The committee reviewed the data presented and the points raised for the appeal, noting in particular that of the cohort looked at by NICE, only 2% were on oral steroids, which was different from the cohort presented for the appeal i.e. a different group of patients were being treated by Dr Spencer. However the committee was also mindful of going against NICE decisions unless there were exceptional local conditions. The committee decided that it could not accept the appeal but was very sympathetic to Dr Spencer's use of omalizumab in a group of patients not fully considered by NICE.
7) Miscellaneous decisions by the APC				
Abatacept	√ R			Recently considered as a treatment option in NICE TA 195 (Rheumatoid arthritis - drugs for treatment after failure of a TNF inhibitor). **Decision** - Approved for addition to the Formulary for use according to NICE guidelines.
Dronaderone	√ R			There has been a recent MHRA alert for Dronaderone, and its association with severe liver injury. Patients now require LFTs prior to treatment, on a monthly basis for six months, at months 9 and 12, and periodically thereafter. **Decision** - Owing to this alert, the traffic light status of dronaderone is changed from BLUE to RED although the Shared Care Group may suggest an alternative.
Escitalopram		See notes		The Medicines Management Committee of NTW Trust had considered an application for escitalopram; the Committee had not been persuaded by the evidence so a request had not been submitted for consideration by the Formulary Subcommittee. The Committee agreed that there was a limited place in therapy for escitalopram and agreed that it should continue as a fourth line treatment, using the non formulary procedure.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Growth Hormone Review	See notes			The Formulary Subcommittee considered a review of growth hormones with a view to rationalising this section of the Formulary. **Decision –** 6. Given that there is no evidence of difference in efficacy and safety between the available preparations Omnitrope® should be used in all de novo paediatric patients. Using Omnitrope® in all de novo patients would realise a maximum recurring saving of £18,500 pa. The uptake of Omnitrope® will be monitored and it is anticipated that it will make up the majority of new prescribing within 12 months. 7. The healthcare professional involved may consider another device is necessary, for example in true needle phobia. Specific criteria should be drawn up to justify the use of the more expensive preparations. 8. Genotropin® MiniQuick will be maintained to ensure availability for patients when travelling. 9. The use of other assay services should be explored to facilitate the use of lower cost rhGH preparations in adult patients. 10. There is an expectation that existing patients, where appropriate, will be switched to the low cost rhGH preparations. This would realise maximum savings of approximately £200,000 pa.
Human Chorionic Gonadotrophin (hCG)	See notes			This is classified as a RED drug for use in fertility treatment. However it has been used for many years in the treatment of hypogonadism which is more appropriate as BLUE. **Decision** – Approved. hCG to be classified as a BLUE drug when used for hypogonadism.
Sitaxentan		See notes		Sitaxentan has been discontinued by the manufacturers and this will be removed from the North of Tyne Formulary.
Venlafaxine (Switching of Venlafaxine MR capsules/tablets to immediate release tablets)	See notes			A proposal was considered for a programme to switch appropriate patients taking venlafaxine modified release (MR) to the same total daily dose of immediate release (IR) venlafaxine tablets. This change would be implemented only for those patients taking doses of up to 225mg daily of modified release venlafaxine. **Decision** – Approved.