North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 14th May 2013 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
Alexander Dyker	Consultant Physician	NUTH
Sue Gordon (SG)	Executive Director Public Health	NHS NoT
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	NHS Newcastle North and East CCG
Helen Seymour	Senior Medicines Management Advisor	NHS NoT
Simon Thomas	Consultant Clinical Pharmacologist	NUTH
Susan Turner (STu) (Professional Secretary)	Medicines Management Advisor	NHS NoT
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Nicola Weaver	GP and Prescribing Lead	NHS Newcastle West CCG
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NHCT/NHSE
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Tamsin Oswald (TO)	Consultant Microbiologist	NHCT
John Ross (JR)	Patient Representative	John Ross (JR)

In attendance

Martin Wright – for item 2013/40	Medical Director	NHS North Tyneside CCG

NoT LPC	North of Tyne Local Pharmaceutical Committee
NHSE	NHS England
NHCT	Northumbria Healthcare NHS Foundation Trust
NHS NoT	NHS North of Tyne
NTWT	Northumberland Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre

2013/38 Declarations of interest

No relevant declarations made.
Members were reminded that annual declarations are due and should be returned in writing to the secretary.

2013/39 Appeals

Plenadren MR

Plenadren is a modified release hydrocortisone preparation that has been designed to more closely mimic the natural circadian rhythm than the immediate release preparation. It has been requested for the treatment of adrenal insufficiency in patients with co-existing diabetes, with brittle control or poor compliance. At the March meeting this application was refused.

Prof Pearce attended to appeal this decision.
He outlined the following points:

- Addison's disease is a rare disease affecting approx 1 in 8000.
- 60% of cases are associated with other auto immune disorders.
- 10% of cases have co-existing Type 1 Diabetes.
- Although cortisone acetate was a huge step forward in the treatment of patients we still have the situation where patients may need oral hydrocortisone up to five times per day.
- In patients with co-existing type 1 diabetes there is difficulty managing the disease when also considering insulin requirements and this can lead to brittle control and potential hospital admission for Addison's crisis.
- Young men under the age of 30 are most at risk of death.
- There is increased mortality with both Addison's disease and type 1 diabetes.
- The aim of treatment is to mimic diurnal cortisol rhythm but this is difficult, often leading to excess glucocorticoid in the afternoon and evening. This is a particular problem in a patient with diabetes.
- He stated that he felt that Plenadren MR is an advance, albeit small, in the treatment options for this particular subset of patients as well as in some patients where compliance is a real issue.
- Beneficial changes in BMI and systolic BP have been demonstrated over short periods of time when using Plenadren MR.
- He acknowledged that whilst the change in HbA1c in the non-diabetic group is not clinically impressive over the 12 weeks of the licensing study, the patients with coexisting Addison's disease and type 1 diabetes had a 0.6% improvement in HbA1c, which he stated is the equivalent change of adding an additional anti diabetic agent for someone with type 2 diabetes.
- Newcastle Upon Tyne Hospitals is a tertiary referral centre, handling the most difficult patients in the North of England.

During questioning the following points were raised:

- The applicant was asked about the potential numbers of patients that may require this product. He indicated that 20 per annum would be a maximum estimate but it was also noted that Northumbria clinicians had stated they may have a similar number.

- Concern was expressed that the numbers, and resulting costs, could extend beyond this. It was stated that there was no intention to extend to all patients, but a desire to use in those with co-existing type 1 diabetes to see if benefits were achieved and in a second cohort of patients where compliance with the hydrocortisone dosing presented difficulties.
- Concern was expressed that the study duration was short and the numbers small. It was acknowledged that the trial was a cross over trial of 2 periods of 12 weeks as requested by the licensing authority and that as only 1 in 80,000 patients have co-existing Addison's and diabetes any larger study would be extremely difficult to undertake.
- It was acknowledged that the plasma profile of steroids in the blood does not mimic those in cells.

The committee noted the above points but were still concerned about the weak evidence base and the practicalities of limiting numbers to the small cohort of patients described.
It was also noted that there is no QALY data available that would demonstrate the cost-effectiveness, in terms of NICE thresholds, of such use.
The committee, on consideration of all of the above, felt unable to overturn the original decision.

Decision: Appeal Refused

2013/40 LDM Structures – QIPP

Dr Martin Wright, Medical Director for North Tyneside CCG attended the meeting to discuss proposed changes to NHS subgroups.
It has been proposed that the QIPP subgroup of the APC evolve to become a Medicines, Guideline and Formulary Review Group (MGFR) which could take on some of the outstanding roles of the QIPP MM board, with an additional focus on guidelines and ongoing review of medicines in use e.g. formulary compliance/audit. It was recognised that the MGFR would need to have clear ToR clarifying the role it would play with regards to medicines use within guidelines, shared care agreements and ongoing audit of formulary compliance.

He further stated that CCGs will now, as commissioners, need to agree the funding of drugs and appliances and therefore further consideration needs to be given to internal CCG processes, and how they link with the APC, to ensure this is done within a robust governance framework whilst continuing to recognise the valuable role that the APC plays in evaluating and considering the cost-effectiveness of medicines.
Dr McEvedy stated that he felt that the role of the APC was a huge strength that CCGs had to call on in terms of local decision making.

It was agreed that further discussion was needed outwith the meeting to sort through some of the issues raised and DC agreed to liaise with MW in order to progress this.

2013/41 Minutes and decision summary from the meeting held on Tuesday 12th March 2013.

These were accepted as a true record.

2013/42 Matters arising not on the agenda.

DC committed at the March meeting to contact Mike Prentice, medical director of the Local Area Team of the NHS Commissioning Board, to seek clarity with

regards to Local Decision making processes and the potential future of a "new" NETAG. He has received indication that there is a proposal currently with CCGs to support such an approach but no final decision had yet been reached. NW emphasised that any such group would require support at an appropriate level to ensure ongoing success.

In the absence of a regional group taking on the previous role of NETAG, a question was raised as to how ongoing review of previous decisions would now be made. Some concern has been expressed that subsequent pricing or clinical information may make historical decisions less relevant than they were at the time of publication.
The committee agreed that until alternative arrangements were made, it would need to pick up any gaps relating to decision making that were the responsibility of CCGs. With regards to current NETAG recommendations the committee was satisfied that clinicians had enough information available to them, through various forums, to allow them to make an informed choice as to both the cost-effectiveness and clinical appropriateness of approved technologies.
The role of the Regional procurement pharmacist in advising relevant parties on proposed commercial schemes was reiterated.

2013/43 Report from the Formulary Sub-committee

Formulary version 4.3 is now available on the APC website.

Minutes and recommendations from the meeting held on 22nd April 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:

Lisdexamfetamine

Lisdexamfetamine dimesylate (Elvanse®) has been requested for the treatment attention deficit/hyperactivity disorder (ADHD) in children aged 6 and over years of age when response to previous methylphenidate treatment is considered clinically inadequate. The request for lisdexamfetamine dimesylate was deferred whilst the views of clinicians from across North of Tyne are sought. There is currently no concensus on the role of this product and further clarity is needed.

Mirabegron

Mirabegron has been requested for treatment of overactive bladder in patients who fail to respond to first line antimuscarinics or who are unable to tolerate antimuscarinic therapy.
NICE has published a positive FAD for mirabegron and is due to publish the TAG in June 2013. It was therefore agreed that the request for mirabegron would be deferred until the NICE TAG was published. Use in line with any TAG recommendations would be supported on publication.

Epiduo® (adapalene 0.1% and benzoyl peroxide 2.5%)

Subsequent to recommending approval of Epiduo, it has become apparent that there is a primary care rebate scheme available in relation to this product. The committee agreed that commercial schemes may be considered providing they meet the principles outlined in previous guidance issued by the regional procurement pharmacist.

2013/44 Report from the Shared Care Group (SCG).

HW highlighted the following points from the minutes of 22/4/13:

- The updated traffic light list is available on the website
- Melatonin - an updated blue information sheet for melatonin was approved by the group which highlights the shared care arrangement now in place for childhood insomnia.
- Acetyl cholinesterase inhibitors information for primary care – this was approved in March but there have been subsequent comments received. The committee agreed that representatives from NTW, secondary and primary care can agree to incorporate these minor changes into an update that will then be approved via chair's action.
- Denosumab blue information sheet – updated with MHRA advice regarding atypical fractures. This was approved.

Giving due consideration to item 2013/40 it was agreed that the Shared Care Group would cease and the work previously undertaken by that group would come under the remit of the Medicines, Guideline and Formulary Review Group. The APC acknowledged the work undertaken by the chairperson and members of the Shared Care Group and thanked them for their commitment to this work. It was suggested that the Medicines, Guideline and Formulary Review Group would benefit from their expertise and that membership of the new group should reflect that.

2013/45 Report from the Anti-microbial Chemotherapy subcommittee.

No report is due.

2013/46 Quality, Improvement, Productivity and Performance (QIPP)

Draft minutes from the meeting on 17 April 2013 were received.

Mrs Seymour highlighted the following points:

A guideline for the prescription of infant formula for infants with suspected cow's milk protein allergy (CMPA) allergy or lactose intolerance has been approved in conjunction with dietitians and was approved for use.

A document to be used when a prescriber is considering alternate medication formulations in patients with swallowing difficulties was received and approved although it was noted that secondary care organisations have internal guidelines relating to the management of such patients and will continue to use these. It is therefore acknowledged that this document has been developed for use in primary care.

2013/47 APC Annual report

Accepted with the proviso that clarification is needed that CCGs were not statutory bodies during 2012/13 and were therefore operating in shadow form during the period covered by this report.

The report will be amended to reflect this and then sent to the chief executives of member organisations.

2013/48 Documents previously circulated by e-mail

None

2013/49 APC Guidelines and Statements for review

None

- APC Guiding Principles on Prescribing Unlicensed Medicines – June 2009. It was agreed that this guidance is obsolete now that the GMC has published new guidance relating to this. It will therefore be removed from the APC website.
- APC Statement on Clopidogrel and PPIs (updated) – July 2010. It was agreed that this document can now be removed from the APC website as current MHRA advice is sufficient.

- APC Guideline on Medicines that are Not Suitable for Generic Prescribing. This document needs some minor updating. Where a product is to be prescribed by brand in line with the recommendations in this document, the preferred brand will be identified in the formulary. The FSC and QIPP group will liaise on completing this work.

2013/50 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 March and April

- TA276 - Cystic fibrosis (pseudomonas lung infection) - Colistimethate sodium and tobramycin.
- TA277 - Methylnaltrexone for treating opioid-induced bowel dysfunction in people with advanced illness receiving palliative care (terminated appraisal due to lack of submission)
- TA278 - Omalizumab for the treatment of severe persistent allergic asthma in children aged 6 and over and adults (review of TA133 and TA201).
- TA280 - Abatacept for treating rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs (rapid review of technology appraisal guidance 234)
- TA281 - Gout - canakinumab (terminated appraisal) because no evidence submission was received from the manufacturer of the technology.
- TA282 - Pirfenidone for treating idiopathic pulmonary fibrosis.

All approved products will be added to the North of Tyne formulary in line with the NICE TAGs.
It was noted that subcutaneous use of abatacept was not considered within the scope of the above TAG as it is a new formulation of this product. There are some potential benefits in terms of administration times and access to Homecare for this product but it was agreed that it should be considered by the FSC before a final decision is made.

2013/51 Chair's action

- Amendment of blood glucose testing document to include line relating to urine testing.
- Amendment to "Comparison of New Oral Anticoagulants with Warfarin in AF – Information for Prescribers" document.

Both of the above documents have had minor changes made to them and the updated versions are now available on the website.

2013/52 Any other business

Somatropin

In March, ML/IC updated the committee on the progress with regards to an ongoing review of growth hormone products undertaken by NUTH in conjunction with their clinicians in order to balance choice with cost. Proposed changes to the formulary layout, which reflect this review, were tabled and approved. IC indicated that further discussion about gain share is required.

Prescriber codes

Changes to NHS structures have meant that prescriber codes need changed and allocated differently with regards to drug and alcohol services, district/community nursing and sexual health, amongst others. HS informed the committee that this work was underway.

Jext
The previously agreed switch to JEXT is now progressing.

2013/53 Date and time of next meeting
Tuesday 9th July 2013 at 12:30pm
Room 3, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.

Signed: ..... **Date:** 9/7/13
(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 May 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
T = 'RED' drugs used in Tertiary Care only.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
Botulinum Toxin A – Bladder dysfunction in paediatrics [u]			√	Botulinum toxin A is currently included in the Formulary (for adult patients) for the treatment of overactive bladders in patients who have failed to respond to conservative treatment. This is an unlicensed indication. It has now been requested for this indication in paediatric patients. **Decision: Bladder dysfunction** – deferred until further data can be provided on whether treatment was successful for patients in whom this treatment has already been tried and the provision of a clear treatment pathway.
2) New Requests				
Lisdexamfetamine (Elvanse®) 30mg, 50mg and 70mg capsules			√	Lisdexamfetamine dimesylate (Elvanse®) has been requested for the treatment of attention deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate. It is a once daily medication with claims of a lower abuse potential than dexamfetamine. **Decision:** The request for lisdexamfetamine dimesylate (Elvanse®) was deferred while the views of clinicians from across North of Tyne are sought.
Epiduo® (adapalene 0.1% and benzoyl peroxide 2.5%) - acne	√			A previous request for Epiduo was rejected in August 2012 on the basis of cost and also because of concerns around efficacy. Low strength (2.5%) benzoyl peroxide preparations have now been discontinued leading to pressure on supplies of the higher strengths. Topical tretinoin has also been discontinued. **Decision**: The request for Epiduo was approved subject to review of usage and if supply issues change.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Mirabegron (Betmiga®) 25 mg and 50 mg tablets			√ Pending NICE	Mirabegron has been requested for treatment of overactive bladder in patients who fail to respond to first line antimuscarinics or who are unable to tolerate antimuscarinic therapy. NICE has published a positive FAD for mirabegron and is due to publish the TAG in June 2013. **Decision**: the request for mirabegron was deferred pending the NICE TAG.
l-lysine 2.5%, l-arginine 2.5% infusion [u]	√			Used for renal protection with lutetium 177 dotatate therapy (approved by the Cancer Drug Fund). There are no major cost implications or safety concerns. **Decision**: l-lysine 2.5%, l-arginine 2.5% solution will be added to the Formulary for use with lutetium 177 dotatate only.
3) New formulations & extensions to use				
Anakinra 100mg injection – Adult Onset Still's Disease	√ R			Anakinra has been requested for use in patients with adult onset Still's disease with an inadequate response to methotrexate. This is an extremely uncommon condition and therefore no large RCTs have been conducted. There is, however, evidence of benefit from small studies. Rheumatologists across the North of Tyne area support the application. **Decision:** The request for anakinra for adult onset Still's disease was approved.
Triptorelin - Prostate Cancer **3mg, 11.25mg and 22.5mg IM injection (Decapeptyl SR)**	√			Triptorelin IM injection has been requested for the treatment of prostate cancer, locally advanced, metastatic and adjuvant to radiotherapy. It was noted that it compared well with regard to cost to the other GnRH analogues. Decapeptyl SR will be an addition to the Formulary rather than a replacement for other products. **Decision:** The request for triptorelin 3mg, 11.25mg, 22.5mg IM injection was approved. Clinicians are encouraged to prescribe the least expensive product that is clinically appropriate.
DC beads – 75-150 micron			√	100–300 micron DC beads have been on the Formulary for several years for the treatment of malignant hypervascularised tumour(s) using the TACE procedure. DC beads 75-150 micron have been requested on the grounds that a smaller bead size could allow more of the intended drug, usually doxorubicin or irinotecan, to be delivered to the tumour. It was noted that while the evidence for 75-100 micron DC beads is not overwhelming, neither is it inferior to the efficacy of 100-300 micron beads. **Decision:** The request was deferred pending further information to support the efficacy of 100-300 micron DC beads and the length of outstanding patents for these drug delivery devices.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
4) Products considered by NESCG and decisions endorsed by APC				
None				
5) Products considered by NICE				
TA276 - Cystic fibrosis (pseudomonas lung infection) - Colistimethate sodium and tobramycin.	√			Approved. The formulary will reflect the NICE TAG.
TA277 - Methylnaltrexone for treating opioid-induced bowel dysfunction in people with advanced illness receiving palliative care	Terminated appraisal due to lack of submission			Noted.
TA278 - Omalizumab for the treatment of severe persistent allergic asthma in children aged 6 and over and adults (review of TA133 and TA201).	√			Approved. The formulary will reflect the NICE TAG.
TA280 - Abatacept for treating rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs (rapid review of technology appraisal guidance 234)	√			Approved. The formulary will reflect the NICE TAG.
TA281 -Gout - canakinumab	Terminated appraisal due to lack of evidence submission			Noted.
TA282 - Pirfenidone for treating idiopathic pulmonary fibrosis.	.√			Approved. The formulary will reflect the NICE TAG.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
6) Appeals against earlier decisions by the APC				
Plenadren (MR Hydrocortisone)		√		Plenadren is a modified release hydrocortisone preparation that has been designed to more closely mimic the natural circadian rhythm compared to the immediate release preparation. It has been requested for the treatment of adrenal insufficiency in patients with co-existing diabetes, with brittle control or poor compliance. At the March 2013 APC meeting it was noted that whilst there is evidence of some improvements in glycaemic control the clinical significance of these changes were unclear and that the number of diabetic patients in the study was low. The application was therefore refused. On appeal the applicant further outlined the reasons for his request but the committee were still not convinced that the level of effectiveness demonstrated justified the associated costs. **Decision: Refused.** The request for Plenadren was not approved.
7) Miscellaneous decisions by the APC				
Calcitonin nasal spray	√			Calcitonin nasal spray has been discontinued and will therefore be removed from the Formulary.
Fesoterodine				Fesoterodine was approved in 2010 on appeal and given a red (hospital prescribing only) status. A request has been received to now change it to a blue status to avoid patients attending regular outpatient appointments. An audit had been undertaken to ascertain whether more aggressive interventions had been avoided by the use of fesoterodine. It was stated that thirty percent of patients prescribed fesoterodine had not required further intervention. Since fesoterodine is currently the fourth anticholinergic product on the formulary it was suggested that mirabegron, once approved, would largely take the place of fesoterodine. **Decision:** Fesoterodine will remain a red drug.