North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 11th January 2011 at Northumbria House, Cobalt Business Park, North Tyneside

Present

Sue Brent (SB)	Director of Pharmacy	RDTC
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
Janet Kelly (JK)	Nurse Clinical Manager	NNTCH
Matthew Lowery (ML)	Trust Antimicrobial Pharmacist	NUTH
Tom McCullough (TM)	Community Pharmacist	
Simon Thomas (ST)	Consultant Clinical Pharmacologist	NUTH
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NECN
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

In Attendance

Paul Dorman (PD) (for item 2011/03a)	Consultant Neurologist, Royal Victoria Infirmary	NUTH
Edmund Ong (EO) (for item 2011/03b)	Consultant Physician for Infectious Diseases, Royal Victoria Infirmary	NUTH

Apologies

Peter McEvedy	GP representative from the PBC community North of Tyne	NHS NoT
Alison Smith	Prescribing Adviser (Provider) – representing prison service	NNTCH
Trevor White	GP representative from the PBC community North of Tyne	NHS NoT

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

Tom McCullough was welcomed to the committee as a Community Pharmacist representative.

2011/01 Minutes of the meeting held on Tuesday 9th November 2010

These were accepted as a true record.

2011/02 Matters arising

2010/67 NHS North East position statement on branded generics

An updated version of this document had been circulated.

2010/70b NPC – APC fitness for purpose review

The expression of interest made to the NPC for them to work with the APC to review decision making across the North of Tyne, has been withdrawn owing to the fact that an 'out of date' toolkit would have been used.

2011/03 Appeals against previous decisions

a) Botulinum toxin type A (Botox®) for the prophylaxis of headaches in adults with chronic migraine – (rejected by APC on 9th November 2010)

Dr Paul Dorman, Consultant Neurologist, Royal Victoria Infirmary attended for this item. Dr Dorman, in presenting the appeal, made the following points:

- Treatment would be reserved for a sub-population of refractory patients with chronic migraine.
- The paper by Dodick et al 2010 had not been taken account of during evaluation of the application. This study was a meta-analysis of the PREEMPT family of trials.
- The PREEMPT programme showed an absolute reduction of about 11% in the proportion of patients reporting severe migraine in the active treatment group.
- Drugs currently used in treatment have significant adverse effects.

The committee reviewed the data presented and points raised for the appeal along with the original evidence submitted. In discussion, the committee felt that:

- There were queries around the marked improvement with the placebo arm of the data
- They were not convinced that this was a 'once off' treatment and that migraines would not reoccur.
- More defined response criteria were needed as currently they were rather vague.
- More precision was needed regarding the patient group to be treated.

The committee were also not persuaded as to the cost effectiveness of the treatment and in conjunction with the above comments, did not feel that there was enough new evidence to reverse its earlier decision not to approve the use of this drug. However, noting that only 56 weeks of data was available so far, the committee felt that a new application could be considered if more data was gathered for cost effectiveness and the above points were addressed.

DECISION: Not approved. The appeal was rejected.

b) Capsaicin 8% patch (Qutenza®) - (rejected by APC on 9th November 2010)

Dr Edmund Ong, Consultant Physician for Infectious Diseases, Royal Victoria Infirmary attended for this item. Dr Ong, in presenting the appeal, made the following points:

- Being applied topically, capsaicin patches lack the drug to drug interactions amongst antiretroviral drugs, especially protease inhibitors.
- Treatment would be a benefit with such patients on a high pill burden.
- Not more than about 6 patients would be considered for this therapy.
- New cohorts of patients would be unlikely to use this product so there would be defined numbers using it for a limited time.
- Use would be restricted to HIV positive patients as their drug regimens are complex.

The committee reviewed the data presented and points raised for the appeal along with the original evidence submitted. The committee did not feel that there was enough new evidence to reverse its earlier decision not to approve the use of this drug. However, in view of the very limited number of patients being considered for treatment with this product, it was felt that Dr Ong could seek to use capsaicin patches via the exceptional funding route. This would be on an individual patient basis.

DECISION: Not approved. The appeal was rejected.

2011/04 Report from the Formulary Sub-committee

a) Minutes and recommendations from the meeting held on Thursday 21st October 2010

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:

- Omalizumab – Following recent NICE guidance, stating that this is not recommended in children aged 6 to 11 years old, it will be removed from the Formulary for this age group. Existing patients are able to continue treatment until it is considered appropriate to stop.
- Prucalopride – A decision on this had been deferred pending a decision by NICE. NICE technology appraisal 211 (Dec 2010) had recommended this as an option in certain specific cases. This would now be added to the Formulary to be used in accordance with NICE.
- Growth Hormone Review – The Formulary Sub-committee will be reviewing this range of products, both those on the Formulary and those not included.

b) Formulary version 2.8 (December 2010)

This version of the Formulary is now available on the APC website.

c) Drugs for erectile dysfunction

This group of drugs were highlighted in the NHS North of Tyne QIPP programme. The Formulary Sub-committee was asked to review this group of products and their placement in the Formulary.

2011/05 Report from the Shared Care Group (SCG)

a) Minutes of the meeting held on Wednesday 15th September 2010

These were noted as having been received. The following points were highlighted:

- The issues around the future of clinical commissioning were noted.

b) Shared care guideline on Immunosuppressive Treatment following Heart and/or Lung Transplants (updated Dec 2010)

This updated guideline was approved and would be placed on the APC website.

c) Traffic light list January 2011

This updated list was approved and would be placed on the APC website.

d) Information leaflets for primary care

The following information leaflets for primary care were approved and would be placed on the APC website in the section for Blue drug information leaflets:

- Dekristol® - Colecalciferol (Vitamin D_3) 20,000 unit capsules
- Agomelatine

2011/06 Report from the Antimicrobial Chemotherapy Sub-Group Minutes of the meeting held on Friday 15th October 2010

These were noted as having been received. The following points were highlighted:

- There were restricted lists of antibiotics in both Newcastle and Northumbria hospitals but they contained different drugs with different restrictions. It was therefore agreed that the antimicrobial section of the Formulary should state that '**antimicrobial agents should be used according to local guidelines**'.

2011/07 Interim Cancer Drug Fund (ICDF)

The positioning of these products on the North of Tyne Formulary was questioned. It was clarified that these products are only approved on a temporary basis and would not be listed in the Formulary document. An appropriate link to the ICDF list currently on the Cancer Network website would be placed on the APC website.

DECISION: Products approved under the Interim Cancer Drugs Fund will not be listed in the North of Tyne Formulary.
ACTION: DCo to arrange for an appropriate link to be placed on the APC website.

2011/08 Non-Formulary Requests

The management of requests for non-formulary drugs was discussed and the merit of having a North of Tyne system. Currently each organisation has its own process and the committee felt that this should not change provided the use of non-formulary drugs was a small percentage of total drug use. Figures would be collated to check this.

ACTION: DCo to collate figures for the use of non-formulary drugs from all organisations and send the results to APC members.

2011/09 Declarations of Interest 2011

Committee members were reminded that new declarations of interest were now due for 2011. Forms had been circulated.

2011/10 Documents previously circulated

These were noted as having been received.

2011/11 Chair's action

Nothing to report.

2011/12 Any other business

a) Use of clopidogrel in TIAs

DCa informed the committee that 'stroke leads' across the North of Tyne are to seek a consensus on how clopidogrel should be used in TIAs. This use is not covered in a recent NICE technology appraisal: 'Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events' – NICE TA 210 (Dec 2010).

b) Interim guidance on provision of oral nutritional support

DCa informed the committee that the above document was being prepared and would be considered at a QIPP meeting next week. It would be sent to APC members for comment but as the deadline for response was short, the committee agreed to DCa taking chair's action on receipt of the comments.

ACTION: DCa to take chair's action on the document on receipt of comments from APC members.

c) Guideline on prescribing proton pump inhibitors (PPIs)

NW reported that the above guideline was now complete and asked if it could be circulated for comment, discussed at QIPP and approved by chair's action. The committee agreed to this approach.

ACTION: DCa to take chair's action on the document on receipt of comments from APC members.

d) NICE TA 195 – Rheumatoid arthritis

MGr reported that the above NICE document had listed abatacept as a treatment option. This might result in a need to review this product which was rejected on appeal at an APC meeting on 18th September 2008. MGr agreed to obtain more details.

ACTION: MGr to obtain more details on NICE TA 195 and the position of abatacept in the treatment of rheumatoid arthritis.

2011/13 Date and time of next meeting

The date of the next meeting is Tuesday 8th March 2011.

Venue: Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park.

Signed: ..... **Date:** 8/3/11

(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 11th January 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				
Leuporelin (Prostap 3®)		See notes		Request for the use of leuporelin as a second line treatment for patients who are unable to tolerate triptorelin was deferred until further evidence could be provided to support the claims that it is associated with fewer side effects, in particular weight gain. No evidence could be found and the application has been withdrawn; however it has been requested that existing patients be allowed to continue their treatment with leuporelin. **Decision** - The request has been withdrawn, but **existing patients** are permitted to continue their treatment with leuporelin.
Prucalopride (Resolor®)	√			A selective, high affinity agonist at serotonin 5-HT_4 receptors, requested for the symptomatic treatment of chronic constipation in women to whom laxatives fail to provide adequate relief. A decision had been deferred pending a decision by NICE. This has now been published as NICE technology appraisal 211 (Dec 2010). **Decision** – Approved for use in line with NICE guidance TA211.
2) New Requests				
Adrenaline Tartrate (Jext®)	√			This formulation of adrenaline tartrate had been requested due to concerns that there is a strong likelihood of future supply problems with the product currently approved for use. Jext® delivers the same adrenaline doses as currently available with Epipen®. However, Jext® differs from Epipen® in that, following administration, a protective needle shield engages and locks, covering the needle, hence removing the risk of needle risk injury. It also has an extended shelf life of 24 months compared to 18 months for Epipen® and this will reduce the likelihood of a patient carrying an out of date auto-injector. It is the same price as Epipen® but due to the extended shelf life, there are potential savings to be made. **Decision** - Approved.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Branded generic combined oral contraceptives	√			Request for various branded combined oral contraceptives (COCs) marketed by Consilient Health. These products have been proven to be bioequivalent to various COCs that are currently already included in the NoT Formulary. These new branded COCs are cheaper than products already included in the NoT Formulary. It is anticipated that these will be included in addition to the existing products, and will be prescribed in new patients. Using alternative COCs will result in substantial cost savings for the NHS without affecting the efficacy or safety of the COCs prescribed. **Decision** – Approved. The six combined oral contraceptives made by Consilient Health should be prescribed for new patients. Prescribers are discouraged from prescribing first line use of brand leaders when the generics are available.
Clostridium Botulinum Toxin A (Azzalure®)		√		Azzalure® has been requested for use in: 1. Treatment of myofascial pain in Masseter and Temporalis muscles that is resistant to all conservative therapies. 2. Treatment of severe bruxism (grinding) or clenching of teeth causing excessive wear of teeth that is resistant to other therapies. 3. Management of hyperhidrosis, in oral and maxillofacial surgery that is commonly encountered as Frey's syndrome post parotidectomy. Dysport® is the product currently used for this indication and Azzalure® is the same strength as Dysport® but has the advantage that it is available in smaller vials which will reduce wastage leading to cost savings. Myofascial pain is routinely managed within NUTH. Failing the use of conservative therapies, pharmacological agents are used systemically to try and modulate the pain. There are cases where both conservative therapies fail and pharmacotherapy is either not tolerated or fails. Bruxism or teeth clenching is so severe that it can cause significant wear of the teeth such that they need rebuilding. Clinical trials have demonstrated that botulinum toxin A is effective in the treatment of bruxism and myofascial pain. **Decision** - The use of botulinum toxin in the treatment of bruxism is not approved as there is insufficient evidence of efficacy as the trials conducted have been too small to assess safety. Dysport® should remain the only product in the Formulary for use in the treatment of hyperhidrosis in Frey's syndrome. Azzalure® is therefore not approved.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Liraglutide (Victoza®)	√			Requested for use in the treatment of adults with type 2 diabetes in line with NICE guidance. Liraglutide has the advantages of once daily administration, and that it can be administered at any time of the day. Liraglutide would only be prescribed in those patients for whom it had clear clinical advantages. **Decision** - Approved as a second line option, in line with NICE guidance, in patients for whom time and frequency of administration is a problem.
Saxagliptin (Onglyza®)		√		A DPP-4 inhibitor requested for use in adult patients aged 18 and over with type 2 diabetes mellitus, to improve glycaemic control. At present, sitagliptin is included in the NoT Formulary for this indication. Saxagliptin is similar to sitagliptin in that it has been demonstrated to have a neutral effect on body weight. NICE guidance does support the use of DPP-4 inhibitors. Saxagliptin is slightly cheaper than sitagliptin, and it has been requested for inclusion in the NoT Formulary in addition to sitagliptin According to the manufacturers, saxagliptin differs from sitagliptin in that it can be used in a reduced dose once daily treatment in end stage renal failure, though this data is yet to be published. **Decision** – Not approved. The potential cost savings were felt not to be great enough to warrant the inclusion in the Formulary of a second gliptin preparation. A new application for saxagliptin could be considered in the future if the product's licence was changed to remove the warning on renal impairment.
3) New formulations & extensions to use				
Aripiprazole solution	√			Aripiprazole is approved for use in the treatment of schizophrenia and bipolar. At present, tablets are the only formulation of aripiprazole included in the NoT Formulary. The addition of aripiprazole solution was requested for patients who have difficulty swallowing the tablets. Aripiprazole solution is very expensive and oro -dispersible tablets are available but not included in the Formulary. The oro-dispersible tablets are available in strengths of 10mg and 15mg, creating difficulties when patients are titrated and multiples of 5mg or less are needed. **Decision** - Approved only for doses of 5mg or less, or when titrating patients on doses of increments of less than 5mg, in patients who have difficulty swallowing tablets. Aripiprazole 10 and 15mg orodispersible tablets to be included in the Formulary for doses over 5mg for those patients who have difficulty swallowing tablets.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Sonovue®	√			Sonovue is a medicinal product that is currently included in the NoT Formulary for use in visualising blood vessels in liver and diagnosing cancer, but it has now been requested for use in contrast endoscopic ultrasound to differentiate between types of cancer of the pancreas. It can sometimes be difficult to differentiate between a benign lesion and the cancer of the pancreas and contrast EUS has better negative predictive value than fine needle aspiration of the lesion. **Decision** – Approved. The current indications of SonoVue are extended to include its use in the diagnosis of pancreatic cancers.
4) Products considered by NECDAG				
No products had been considered by NECDAG for addition to the Formulary.				
5) Products considered by NETAG				
No products had been considered by NETAG for addition to the Formulary.				
6) Appeals against earlier decisions by the APC				
Botulinum toxin type A (Botox®)		√		Requested for the prophylaxis of headaches in adults with chronic migraine. The current management of chronic migraine involves using drugs such as tricyclic antidepressants and anticonvulsants. Botox® is a new treatment option and involves injections into the muscles of the neck and head. Whilst there appear to be no safety concerns with the use of Botox® in this indication, the evidence put forward is not clinically significant and costs are relatively high. An application was considered and refused by the APC at its meeting on 9th November 2010. **Decision** – Not approved. The committee reviewed the data presented and points raised for the appeal along with the original evidence submitted. In discussion, the committee felt that: • There were queries around the marked improvement with the placebo arm of the data • They were not convinced that this was a 'once off' treatment and that migraines would not reoccur. • More defined response criteria were needed as currently they were rather vague. • More precision was needed regarding the patient group to be treated. The committee were also not persuaded as to the cost effectiveness of the treatment and in conjunction with the above comments, did not feel that there was enough new evidence to reverse its earlier decision not to approve the use of this drug. However, noting that only 56 weeks of data was available so far, the committee felt that a new application could be considered if more data was gathered for cost effectiveness and the above points were addressed.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Capsaicin 8% patch (Qutenza®)		√		A topical analgesic requested for use in the treatment of neuropathic pain in HIV patients and other non-diabetic patients. Qutenza® offers pain relief following a single 30 to 60 minute application every 90 days, and it is anticipated that this may reduce the risk of patient non compliance often encountered using medication requiring more demanding treatment regimens. A maximum of 4 patches can be applied every 90 days. An application was considered and refused by the APC at its meeting on 9th November 2010. **Decision** – Not approved. The committee reviewed the data presented and points raised for the appeal along with the original evidence submitted. The committee did not feel that there was enough new evidence to reverse its earlier decision not to approve the use of this drug. However, in view of the very limited number of patients being considered for treatment with this product, it was felt that the applicant could seek to use capsaicin patches via the exceptional funding route. This would be on an individual patient basis.
7) Miscellaneous decisions by the APC				
Insulin KwikPens®	√			Lilly are discontinuing the Humalog® pens and the alternative is the KwikPen®. There would be no additional costs. **Decision** – Approved. Insulin KwikPen® to be added to the Formulary.
Omalizumab in children aged 6-11 years old		See notes		Omalizumab is included in the NoT Formulary for use in children aged 6-11 years old. NICE has recently published guidance for the use of omalizumab in children. The guidance states that omalizumab is **not** recommended for the treatment of severe persistent allergic asthma in children aged 6 to 11 years. Children currently receiving omalizumab for the treatment of severe persistent allergic asthma should have the option to continue treatment until it is considered appropriate to stop. **Decision** - Omalizumab for use in children aged 6-11 years to be removed from the Formulary.