North of Tyne
Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 11th May 2010 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)	Head of Pharmacy Clinical Governance	NTWT
Rosie England (RE)	Head of Medicines Management	NHS NoT
Matt Grove (MGr)	Consultant Rheumatologist, NTGH	NHCT
Mike Guy (MGu)	Medical Director	NHS NoT
Mike Hannon (MH)	Community Pharmacist/North of Tyne PEC	NHS NoT
Zahra Irannejad (ZI)	Head of Prescribing	NNT&N
Janet Kelly (JK)	Nurse Clinical Manager	NNTCH
Matthew Lowery (ML)	Trust Antimicrobial Pharmacist	NUTH
Dominic McDermott (DM) (for Bhavana Reddy)	Senior Pharmacist	RDTC
Peter McEvedy (PM)	GP representative from the PBC community North of Tyne	NHS NoT
Alison Smith (AS)	Prescribing Adviser (Provider) – representing prison service	NNT&N
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Trevor White (TW)	GP representative from the PBC community North of Tyne	NHS NoT
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Sue Gordon	Consultant in Public Health Medicine	NHS NoT
Bhavana Reddy	Acting Director of Pharmacy	RDTC
Simon Thomas	Consultant Clinical Pharmacologist	NUTH
Steve Williamson	Consultant Pharmacist in Cancer Services	NECN

NECN	North of England Cancer Network
NHCT	Northumbria Healthcare NHS Foundation Trust
NHS NoT	NHS North of Tyne
NNT&N	Newcastle, North Tyneside & Northumberland PCOs
NTWT	Northumberland Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre

2010/24 Minutes of the meeting held on Thursday 11th March 2010

These were accepted as a true record.

2010/25 Matters arising

2009/20 NHS Constitution and NPC documents on clinical decision making

DM reported that he had sent a draft report on the National Prescribing Centre (NPC) event to directors of commissioning and CEOs of NHS organisations in the North East. As a result the clinical decision making processes throughout the

North East SHA would be reviewed.
RE reported that she had obtained a copy of an Ethical Framework document from the West Midlands that supported the clinical decision making process. Sue Gordon was looking to see if the principles in this document could be adopted in the North of Tyne.
RE also reported that progress was being made in areas identified in the NPC diagnostic tool for clinical decision making. This tool would be used to re-audit the clinical decision making process North of Tyne in 6 months.

ACTION: RE to set up a task group to re-audit the clinical decision making process North of Tyne using the NPC diagnostic tool.

2010/17a Shared Care Group – LMC representation
MGu clarified that Jane Lothian now represented both North Tyneside and Northumberland Local Medical Committees (LMCs) on the Shared Care Group and that John Warrington represented the North of Tyne PBC community.

2010/22 Clopidogrel
A letter had been sent to pharmacy chains restating the position of generic clopidogrel within the North of Tyne health economy.
RE agreed to monitor the uptake of generic clopidogrel in primary care. This highlighted the need to look at mechanisms of controlling and auditing APC decisions.

2010/26 Appeal against previous decisions
No appeals had been received.

2010/27 Report from the Formulary Sub-committee

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

- Dyes, Patent Blue and Methylthioninium Chloride – Information collected on the use of these products has highlighted the risk of anaphylactic reactions with patent blue which was only being used in two operating theatre locations at the RVI. The use of methylthioninium chloride is more widespread and although licensed, it is widely used for unlicensed indications. Risks associated with its use have been highlighted in a recent MHRA Drug Safety Bulletin. Further information on the use of these products will be considered at the next meeting of the Formulary Sub-committee.
- Mesalazine – A document summarising the comparative properties and costs of the different oral 5-aminosalicylate preparations, used in the management of inflammatory bowel disease, had been circulated. Consideration was given to the possibility of adding Asacol® 800 and Mezavant® XL to the formulary, and of using Mesren® MR instead of Asacol® 400 as the first choice. Gastroenterologists have been contacted for comments.
- The committee discussed the fact that a variety of guidelines had been developed across the North of Tyne by a guidelines group, chaired by Stephen Blair. It was felt that the APC should establish a link with this group, to ensure that there was consistency between any guidelines developed and the North of Tyne Formulary.

ACTION: DCa to contact Stephen Blair to see how a link could be established between the NHS North of Tyne guidelines group and the APC.

b) HRT Formulary recommendations

This section of the formulary was due to be reviewed and a document had been prepared and circulated to appropriate clinicians. The majority of their suggested changes were accepted. However, it was decided that evaluations should be made for Premique® low-dose, Utrogestan® and Evorel® Sequi.

Intrinsa® was requested by the clinicians but as this had previously been refused by the APC (May 2008), a new application with new evidence would be required if this was to be included in the Formulary.

c) Caphosol® and MuGard®

Both these topical oral agents were requested for the treatment of oral mucositis. Although the committee would have preferred a standard treatment, it recognised that both had benefits. MuGard® was approved for general use but, owing to its high cost, Caphosol® was only approved for use by Dr Charles Kelly, in those patients having chemo- radiotherapy or radiotherapy for malignancies of the oral cavity, hypopharnyx and oro-pharynx.

The use of both products will be reviewed during the next 6 months with a formal report to the APC being required as a condition of approval.

d) Pregabalin and amitriptyline in neuropathic pain management

NICE clinical guideline CG96 (The Pharmacological management of neuropathic pain in adults in non-specialist settings) was discussed in regards to the note that pregabalin should be offered as first-line treatment alongside amitriptyline. The NICE guidance was considered and it was felt that, as gabapentin was as effective as pregabalin, it was still appropriate to use gabapentin before pregabalin, especially when the more cost effective lower strength capsules were used.

Therefore the Formulary would be amended to state:

For neuropathic pain –

First choice – amitriptyline

Second choice – gabapentin

Third choice – pregabalin

Alternatives – as currently listed including the use of tramadol in line with the NICE guideline.

For painful diabetic neuropathy –

First choice – duloxetine

Second choice – amitriptyline

Third choice – gabapentin

Fourth choice – pregabalin

Alternatives – as currently listed including the use of tramadol in line with the NICE guideline

2010/28 Report from the Shared Care Group (SCG)

a) Minutes of the meeting held on Wednesday 17th March 2009

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

- Monitoring of DMARDs – MGr reported that negotiations to facilitate this were ongoing.
- Commissioning issues – these were now improving.

- Lanreotide – This will be prescribed by clinicians from Newcastle Hospitals and recharged to primary care.

b) Information leaflets for primary care
The following information leaflets for primary care were approved, subject to some minor amendments in places, and would be placed on the APC website in the section for Blue drug information leaflets:

- Acetylcysteine
- Ibandronic acid
- Lidocaine plasters
- Rosuvastatin
- Rotigotine patches
- Triptorelin

2010/29 Report from the Antimicrobial Chemotherapy Sub-Group
a) Updated Primary Care Antibiotic Guidelines
Subject to some minor amendments, these were approved and would be placed on the APC website.

2010/30 Monitored dosage systems/compliance aids
DCa reported that some flow diagrams relating to the process of using compliance aids had been developed but these were not in their final form. Also a risk assessment tool and guidance notes still need to be developed. RE, ZI and NW agreed to look into how to move forward with this issue.

ACTION: RE, NW and ZI to develop a process for moving forward with this issue.

2010/31 APC statement on Clopidogrel and proton Pump Inhibitors
The committee noted that this had now been withdrawn from the APC website.

2010/32 APC Annual report 2009-10
This is currently being prepared and suggestions for inclusion were welcomed.

2010/33 Documents previously circulated
These were noted as having been received.

2010/34 Chair's action
Nothing to report.

2010/35 Any other business
No other business was discussed.

2010/36 Date and time of next meeting
The date of the next meeting is Tuesday 13th July 2010.
Venue: Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park.

Signed: ..... **Date:** 13/7/10
(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 May 2010.**

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				
Urgosorb®			√	Sterile alginate/ hydrocolloid dressing designed to combine the properties of both types of dressing with high absorbency. Requested with a view to it replacing Aquacel® in the Formulary. **Decision -** Deferred pending the receipt of further information and discussion with the Tissue Viability Group.
2) New Requests				
Caphosol®	√ R T See notes			A topical oral agent that lubricates the mucosa and may help to maintain the integrity of the oral cavity through its mineralizing potential. The distinguishing feature of Caphosol® is its high concentrations of calcium and phosphate ions. It is the only licensed product available for the use in Radiotherapy or Chemotherapy induced mucositis, and reports from Head and Neck Cancer Centres in North America suggest that it is superior to barrier gels. Requested as a first-line treatment in those patients having chemo- radiotherapy or radiotherapy to malignancies of the oral cavity, hypopharnyx and oro-pharynx. **Decision** – Approved for use by Dr Charles Kelly only, in those patients having chemo- radiotherapy or radiotherapy to malignancies of the oral cavity, hypopharnyx and oro-pharynx. The use of Caphosol® will be reviewed during the next 6 months with a formal report to the APC being required as a condition of approval.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Cetrorelix acetate 3mg injection (Cetrotide®)	√ R			The first LHRH antagonist to be marketed in the UK. The 3mg injection has been requested for the inhibition of premature LH surges in women undergoing controlled ovarian stimulation. In clinical studies, cetrorelix was of similar efficacy to the gonadorelin analogues buserelin and triptorelin. It offers a shorter and simpler protocol for controlled ovarian stimulation compared with those using gonadorelin analogues. Cetrorelix® is more expensive than other agonists used in ovarian stimulation but use is likely to be minimal. **Decision** – The 3mg injection is approved for use.
Dronaderone (Multaq®)	√ B			A class III antiarrhythmic drug requested for use by cardio electrophysiologists for use in those patients who are unsuitable or not tolerant of amiodarone. It is felt to have a more favourable safety profile than amiodarone. Initiation of therapy will be carried out by cardio electrophysiologists and it is anticipated that primary care would continue to prescribe dronedarone once the patient is deemed stable. **Decision** - Approved for the limited use that has been requested, until full NICE guidance is published. Initiation of therapy restricted to cardio electrophysiologists.
Fesoterodine (Toviaz®)		√		Selective muscarinic antagonist requested for second-line use in the management of overactive bladder. An application for fesoterodine for the same indication was rejected by the APC on 25th November 2008 on the grounds that the evidence available did not demonstrate any meaningful advantages over products currently used. A new request has been submitted on the grounds of recent clinical evidence being available. **Decision** - Refused. A slight improvement in efficacy has been demonstrated, but these are not sufficient grounds to approve fesoterodine.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
MuGard®	√			A ready-to-use mouth rinse for the prevention and management of the lesions and symptoms of oral mucositis, in particular caused or induced by radiation and/or chemotherapy. It is a muco-adhesive oral rinse and forms a protective coating. It has been requested for patients who are currently on sunitinib (Sutent®) treatment, and is cheaper than treatment currently used. **Decision** – Approved. The use of MuGard® will be reviewed during the next 6 months with a formal report to the APC being required as a condition of approval.
Sterile Sodium Chloride 7% (Hypertonic Saline)	√ See notes			Requested for use in cystic fibrosis patients, non-CF related bronchiectasis and COPD patients. The inclusion criteria for use will be for patients with persistant mucus. It is the only 7% nebulised sodium chloride product available, and is cheaper than the current treatment on the Formulary, 6% hypertonic sodium chloride solution (Mucoclear®) There have been concerns about the poor labelling of these products. However, the manufacturers of 7% hypertonic sodium chloride have confirmed that they will be labelling each individual amp with the words 'use for nebulisers only'. **Decision** - Approved for use in the treatment of patients with CF and bronchiectasis. At this time, it is NOT approved for use in the treatment of COPD unless evidence of its efficacy within that group of patients is provided.
3) New formulations & extensions to use				
Forceval® Capsules	√			Requested for use as an oral supplement in patients with severe anorexia nervosa who are severely malnourished. It is one of the few licensed products for this indication to contain a combination of a range of minerals and trace elements. Forceval® has previously been approved for use on specialist advice in patients with metabolic disorders, burns patients with malnutrition or alcohol dependency and severe burns patients following discontinuation of IV nutrition containing trace elements. **Decision** - Approved for use in patients with severe anorexia nervosa.
Salbutamol Easyhaler®	√			Requested for use in children and patients with reduced manual dexterity and those with breath/device actuation co-ordination problems. The only other dry powdered device, Turbohaler®, is difficult for patients to use correctly and effectively. It is available in two strengths and will be used in addition to the Accuhaler® device, which is more expensive **Decision -** Approved for use in children only, as a second line treatment after the Accuhaler®. There should be a review of the number of patients prescribed the Easyhaler® after six months.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
4) Products considered by NECDAG				
No products had been considered by NECDAG.				
5) Products considered by NETAG				
Bosentan (Tracleer®)		√		An appraisal was conducted for the use of bosentan in the management of digital ulcers in patients with systemic sclerosis. **Decision** – Not approved for use within NHS North East.
Deferasirox (Exjade®)	√ See notes			An appraisal of deferasirox was conducted for the treatment of chronic iron overload in patients with haemolytic anaemias such as beta-thalassaemia and sickle cell anaemia. **Decision** – Only recommended for use when treatment with desferrioxamine is no longer considered to be appropriate due to progressive iron overload despite maximally tolerated doses of desferrioxamine. Continued treatment with desferrioxamine might not be considered appropriate in cases of confirmed intolerance, hypersensitivity, or persistent non-compliance with therapy.
Gastroelectrical stimulation for gastroparesis		√		An appraisal was conducted of gastroelectrical stimulation using the Enterra® device for the management of gastroparesis. **Decision** – Not approved
6) Appeals against earlier decisions by the APC				
No appeals were considered by the APC.				
7) Miscellaneous decisions by the APC				
Eye caps®/Ocuvite®		√		The Formulary Subcommittee was asked to consider evidence to indicate that some nutritional products may be of use in helping to slow down deterioration of vision in patients with the common form of age related macular degeneration. **Decision** – Refused. There is insufficient evidence to endorse the use of these products.
Cabergoline and pergolide	See notes			Cabergoline and pergolide were reviewed as to whether they should both remain in the Formulary. The use of pergolide is minimal, and cabergoline is being prescribed to a number of patients within endocrinology. **Decision -** Pergolide to be removed from the Formulary and there should be a review of patients currently prescribed pergolide. Cabergoline to remain in the Formulary for initiation by endocrinologists. Clarification as to the specific indications for which cabergoline is being used is being sought from endocrinologists and neurologists. Parkinsonism to be removed as an indication.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Pregabalin and amitriptyline in neuropathic pain management	See notes			NICE clinical guideline CG96 (The Pharmacological management of neuropathic pain in adults in non-specialist settings) was discussed in regards to the comment that pregabalin should be offered as first-line treatment alongside amitriptyline. **Decision** – The NICE guidance was considered and it was felt that it was still appropriate to use gabapentin (the use of lower strength capsules being more cost effective). Therefore the Formulary would be amended to state: **For neuropathic pain** – First choice – amitriptyline Second choice – gabapentin Third choice – pregabalin Alternatives – as currently listed including the use of tramadol in line with the NICE guideline **For painful diabetic neuropathy** – First choice – duloxetine Second choice – amitriptyline Third choice – gabapentin Fourth choice – pregabalin Alternatives – as currently listed including the use of tramadol in line with the NICE guideline.
Ustekinumab	√ R			This monoclonal antibody was considered for the treatment of adults with moderate to severe psoriasis in NICE technology appraisal guidance No. 180 (Sep 2009) which states: Ustekinumab is recommended as a possible treatment for people with plaque psoriasis if: • standard assessments show that their psoriasis is severe and is affecting their quality of life **and** • their psoriasis has not improved with other treatments such as ciclosporin, methotrexate or PUVA (psoralen and long-wave ultraviolet radiation), or they have had side effects with these treatments in the past or there is a medical reason why they should not be given them. The manufacturer of ustekinumab has agreed to a 'patient access scheme' which means that they provide the higher dose needed for people who weigh more than 100 kg at the same total cost as the lower dose for people who weigh 100 kg or less. Ustekinumab treatment should be stopped if standard assessments show that a person's psoriasis has not clearly improved after 16 weeks. **Decision** – Approved for use in line with NICE recommendations.