North of Tyne
Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 12th July 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
Helen Coundon (HC)	GP Consortia representative, Engage Health	
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Alexander Dyker (AD)	Consultant Physician	NUTH
Rosie England (RE)	Associate Director of Medicines Management	NHS NoT
Janet Kelly (JK)	Nurse Clinical Manager	NHCT
Kirsty Macfarlane (KM) (for Sue Brent)	Principal Pharmacist, Medicines Management	RDTC
Tom McCullough (TM)	Community Pharmacist	
Peter McEvedy (PM)	GP representative from the PBC community North of Tyne	NHS NoT
Simon Thomas (ST)	Consultant Clinical Pharmacologist	NUTH
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Lindsey White (LW) (for Zahra Irannejad)	Prescribing Advisor	NNTCH
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NECN
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH Medicines Management Committee.	NUTH

In Attendance

Alan Horgan (AH) (for item 2011/40a)	Consultant Colorectal Surgeon, Freeman Hospital.	NUTH
Anthony Desoyza (AD) (for item 2011/40b)	Consultant in Respiratory Medicine, Freeman Hospital.	NUTH
Sarah Chandler	Senior Clinical Pharmacist - Formulary	NHCT

Apologies

Sue Brent	Director of Pharmacy	RDTC
Sue Gordon	Executive Director of Public Health	NHS NoT
Matt Grove	Consultant Rheumatologist, NTGH	NHCT
Mike Guy	Medical Director	NHS NoT
Zahra Irannejad	Head of Prescribing	NNTCH
Matthew Lowery	Formulary and Audit Pharmacist	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

DCa reported that Alison Smith was no longer in post and as such, was no longer a member of the committee. APC representation for the prison service was being investigated.

2011/39 Minutes of the meeting held on Tuesday 10th May 2011
These were accepted as a true record.

2011/40 Matters arising
2011/22 NPC Diagnostic Tool review
A document had been circulated. It was agreed that this topic should be dealt with as part of the review of the APC's Terms of Reference.

2011/37a Diamorphine to Morphine switches
NW reported that the group had met to review palliative care drugs across North of Tyne. Parenteral products had been included in the review and a document would be ready for the next APC meeting.

2011/37d Professional Secretary of the APC
RE reported that Susan Turner would be taking on this role on the departure of DCo.

2011/41 Appeals against previous decisions
a) Tisseel® (reviewed by APC on 10th May 2011)
Mr Alan Horgan, Consultant Colorectal Surgeon, Freeman Hospital attended for this item. Mr Horgan, in presenting the appeal, made the following points:

- Chronic groin pain was often present after hernia repair.
- Tisseel® was found to be more effective than staples, in that there was less groin pain and better recovery in patients treated with Tisseel®.
- Previous price comparisons between glues and staples were now out of date as the price of staples had increased considerably.

The committee reviewed the points raised for the appeal along with the original evidence submitted.
The committee accepted the appeal and agreed to change its original decision so that Tisseel® Lyo, the current product on the North of Tyne Formulary, could be used in mesh fixation hernia repairs. The proposal to replace Tisseel® Lyo with Tisseel® Ready-Mix would be considered as part of a review of fibrin sealants.

DECISION: Approved. Tisseel® Lyo approved for use in mesh fixation hernia repairs.

b) Indacaterol (reviewed by APC on 10th May 2011)
Dr Anthony Desoyza, Consultant in Respiratory Medicine, Freeman Hospital attended for this item. Dr Desoyza, in presenting the appeal, made the following points:

- Treatment with Indacaterol showed improvements in breathlessness when compared with Tiotropium.
- Indacaterol presents an alternative device for patients who have difficulties with other product devices.
- A once daily dosing regimen would aid compliance in patients with COPD.
- Prices are similar to comparable products
- Patients currently on Tiotropium would probably not be switched to Indacaterol as this would tend to be for new patients.

The committee reviewed the data presented and the points raised for the appeal along with the original evidence submitted. The committee did not feel that there was enough evidence to reverse its original decision not to approve the use of this drug. The committee also felt that there was scope for a review of the various treatment options for COPD, especially the inhaled products.

DECISION: Not approved. The appeal was rejected.

2011/42 Report from the Formulary Sub-committee

a) Minutes and recommendations from the meeting held on Thursday 30th June 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 point was highlighted:

- Loteprednol eye drops – It had been confirmed that rimexolone would be retained on the Formulary but reviewed in 12 months.

2011/43 Report from the Shared Care Group (SCG)

a) Minutes of the meeting held on Wednesday 15th June 2011

These were noted as having been received.

b) Shared care guideline - Immunosuppressive treatment following paediatric renal transplantation

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

c) Updated shared care guideline - Immunosuppressive treatment following renal transplantation

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

d) Updated shared care guideline - Immunosuppressive treatment following heart and lung transplants.

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

e) Updated shared care guideline - Immunosuppressive treatment following liver transplants

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

f) Shared care guideline – Dexamfetamine for the treatment of ADHD in children and young people.

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

g) Updated shared care guideline – AchEIs for dementia

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

h) Shared care guideline on Dronedarone

This guideline was approved clinically but could not be placed on the APC website at this point in time owing to some outstanding commissioning issues.

i) Information leaflets for primary care

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

(a) Dexamfetamine for primary sleep disorder

(b) Chorionic Gonadotrophin (Pregnyl®) – use for secondary hypogonadism in adult males.

2011/44 Report from the Antimicrobial Chemotherapy Sub-Group
No meeting of this sub-group had been held.

2011/45 Report from the Medicines Management QIPP Sub-Group
The minutes of a meeting held on Tuesday 14th June 2011 were noted.

2011/46 Review of the APC Terms of Reference
As there was no time to discuss this topic, the chair agreed to develop a draft document for discussion at a future meeting.

ACTION: DCa to prepare a draft Terms of Reference document for discussion at a future meeting of the APC.

2011/47 Prescribing responsibilities – definition of specialist and urgent medicines
The APC had been asked to define the term specialist and urgent medicines as noted in the 'Treatment Recommendation Form' used by secondary care clinics to refer prescribing to primary care. These two categories form the exception whereby hospital clinicians should initiate prescribing rather than refer.
It was noted that within the Formulary, the entries for medicines labelled as 'specialist' were being updated to include more detail to aid prescribers. The term 'urgent' was felt to be determined more on a case by case basis.

2011/48 APC Annual report 2010-11
The APC report was ratified by the committee.

ACTION: DCo to circulate the annual report to CEOs of participating organisations and place the document on the APC website.

2011/49 Documents previously circulated
These were noted as having been received.

2011/50 Chair's action
Nothing to report.

2011/51 Any other business
a) Durham and Darlington APC
The above committee has recently been established and requested adoption, through membership, of the North of Tyne Formulary Sub-committee processes to avoid duplication in drug evaluation. The committee supported this development with an assumption that the 6 new members would assist with appropriate workload as necessary.

Date and time of next meeting
The date of the next meeting is Tuesday 13th September 2011.
Venue: Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park.

Signed: ..... **Date:** 13/9/11
(Chair of the APC)

North of Tyne
Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 12th July 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 = 'RED' 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				
Fentanyl Citrate - Sublingual (Abstral®)			√	Sublingual fentanyl citrate (Abstral®) has previously been refused by NETAG for its licensed indications but is now being requested for the rapid relief of sudden pain on movement for patients undergoing radiotherapy. Actiq®, the product currently used for this indication, takes fifteen minutes to take effect whereas Abstral® is effective within ten minutes. **Decision** – Deferred. Specialists to be asked to provide safety data. The application to be re-considered if sufficient data is provided.
Loteprednol eye drops (Lotemax®)	√			A new locally acting corticosteroid. In known corticosteroid responders, loteprednol had a lower propensity than prednisolone acetate to increase intraocular pressure (IOP). A rise in IOP can occur as an adverse effect of corticosteroid therapy. Weaker corticosteroid eye drops, such as rimexolone, induce less IOP but are much less effective anti-inflammatory agents, compared to the more potent conventional corticosteroids. **Decision** - Approved as a second line agent to conventional corticosteroid eye drops.
3) New formulations & extensions to use				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Apomorphine pre-filled syringes (Apo-go®)		√		Apomorphine is a dopamine agonist, which is usually prescribed to provide additional or alternative benefit for people who have had Parkinsons Disease for some time. At present apomorhine is administered by injection or infusion. The prefilled syringes are an easier to use presentation containing a 5mg/ml concentration of apomorhine hydrochloride which is ready to transfer to a plastic syringe specifically designed to use with an Apo-go pump. **Decision** - Not approved. A new application can be considered if there is further evidence to demonstrate the advantages of the pre-filled syringes over the current method of administration.
Basiliximab-GVHD (Simulect®)	√ R			Requested for the treatment of severe graft versus host disease post haematopoitetic stem cell transplantation on the grounds that there is no longer an alternative treatment option available, due to the discontinuation of dacilizumab. First line treatment for aGVHD is steroids, followed by steroids plus infliximab and then steroids plus infliximab and basiliximab. It is used for acute GVHD but not as first line treatment, so the condition will be severe or refractory by the time that it is used. **Decision** - Approved.
Cetrorelix 0.25mg injection (Cetrotide®)	√			A single dose regimen of Cetrorelix is included in the NoT Formulary for use in cases where LH surges need to be inhibited more quickly. Most units in the UK that currently use LHRH antagonists as their default stimulation regimen are using multidose protocols. The single dose regimen is required to be administered at a precise time and this problem can be overcome by using the multiple dosing regimen. **Decision** – Approved. The number of patients involved is low, and an extension to include this indication would result in a small cost increase.
Juvederm Ultra 4®	√			Juvederm Ultra 4® is licensed and has been requested for use for volumising and correction of deeper folds and wrinkles, including enhancing volume in the cheeks and chin. Juvederm 4® has more cross linking than Juvederm 3®; hence it has a greater volumising capacity. **Decision** - Approved for use in the treatment of severe facial wrinkles and folds. **Note: The procedure for which Juvederm ultra® is used is NOT available on the NHS.**

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Methylphenidate-giggle incontinence	√ A			Requested for the treatment of giggle incontinence (GI) in children aged 8 to 16 years old. There is substantial experience of using methylphenidate in the treatment of ADHD and the doses used in GI are considerably less than those prescribed in ADHD. Other treatments such as antimuscarinics (e.g. oxybutynin) have little evidence base and are rarely successful. Successful treatment of GI with methylphenidate will potentially increase the child's quality of life by reducing the possibility of social embarrassment and bullying. **Decision** - Approved for use as a third line option in the treatment of giggle incontinence. Its use should be subject to a therapeutic trial to be reviewed after two months and considered for shared care if patients have been shown to respond after the trial period.
Nicorette Quickmist®		√		Requested for use for abrupt cessation of smoking. It is used by holding the spray as close to the individuals mouth as possible. In most cases smokers will require 2 sprays per dosage and 4 sprays per hour. Studies have demonstrated that it provides rapid absorption of nicotine and higher plasma concentrations of nicotine in the first 10 minutes after dosing than alternative products. It has been claimed that it may be used more discreetly which may improve patient compliance. It is considerably more expensive than other products available. **Decision** - Not approved. The committee was not convinced that the suggested benefits justified the increased cost.
4) Products considered by NECDAG				
Dasatinib		√		Considered for treatment of newly diagnosed Philadelphia chromosome positive chronic myeloid leukaemia (CML) in the chronic phase. **Decision** – Not approved.
Mitomycin C and 5-Fluorouracil for bladder cancer concurrent with radiotherapy	√ R			Considered for the treatment of bladder cancer concurrent with radiotherapy. There is a growing body of research which supports the use of concurrent chemotherapy in bladder cancer with most people considering it the new standard of care for patients in reasonable condition having radiotherapy. **Decision** – Approved from NHS standard funding pathways.
Nilotinib		√		Considered for treatment of newly diagnosed Philadelphia chromosome positive chronic myeloid leukaemia (CML) in the chronic phase. **Decision** – Not approved.
Sorafenib		√		Considered for the treatment of advanced thyroid cancer. **Decision** – Not approved.
5) Products considered by NETAG				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
No products had been considered by NETAG for addition to the Formulary.				
6) Appeals against earlier decisions by the APC				
Indacaterol (Onbrez Breezhaler®)		√		A novel rapid onset of action inhaled long acting β_2 agonist providing 24 hour bronchodilation at once daily dosing. An application was considered and refused by the APC at its meeting on 10th May 2011. **Decision** – Not approved. The committee reviewed the data presented and the points raised for the appeal along with the original evidence submitted. The committee did not feel that there was enough evidence to reverse its original decision not to approve the use of this drug.
Tisseel® Ready Mix	√			Requested for use in mesh fixation in hernia repairs. At present, Tisseel® Lyo is included in the North of Tyne Formulary. Tisseel® products have recently gained a new license indication to include mesh fixation in hernia repair. Tisseel® Ready Mix is deep frozen and requires minimal preparation. An application was considered and refused by the APC at its meeting on 10th May 2011. **Decision** – Approved. The committee accepted the appeal and agreed to change its original decision so that Tisseel® Lyo, the current product on the North of Tyne Formulary, could be used in mesh fixation hernia repairs. **Note**: The proposal to replace Tisseel® Lyo with Tisseel® Ready-Mix would be considered as part of a review of fibrin sealants.
7) Miscellaneous decisions by the APC				
Cilostazol and Naftidrofuryl Oxylate	√ See notes	√ See notes		Following on from NICE TAG 223 – Treatment of intermittent claudication in people with peripheral arterial disease, cilostazol is no longer recommended in this indication and naftidrofuryl oxylate is noted as a treatment option. **Decision** – Cilostazol to be removed from the Formulary for this indication and naftidrofuryl oxylate to be added.
Clotrimazole dusting powder and Miconazole spray powder	√ See notes			Clotrimazole 1% dusting powder has now been discontinued and the cheapest alternative that is available is Miconazole spray. **Decision** - Miconazole spray powder to replace Clotrimazole dusting powder in the North of Tyne Formulary.
Co-trimoxazole 960mg tablets	√			Co-trimoxazole 480mg tablets are included in the NoT Formulary. Previously 2x 480mg co-trimoxazole had been used in preference to 960mg tablets on the grounds of cost; it is now more cost effective to use 960mg tablets. **Decision** - Co-trimoxazole 960mg tablets to be reinstated in the North of Tyne Formulary.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Dimeticone 4% lotion (Hedrin®)	√			Hedrin® is offered by the 'Pharmacy First' scheme, but it is not included in the NoT Formulary. It is a non pesticide based lotion and can be used in patients with contraindications to standard pesticide based treatments. **Decision** - Approved for inclusion in the North of Tyne Formulary.
Epipen®	√			The APC had previously approved the replacement in the Formulary of Epipen® with Jext®. However, Jext® will not be available until later in the year and a request has been made to reinstate Epipen® until that time. **Decision** - Epipen® to be reinstated in the North of Tyne Formulary until Jext® is available.
Gender dysphoria	√ R			The APC had been asked to decide the Formulary status of the drugs used in the treatment of gender dysphoria. It was noted that all of the drugs that would be used in this indication are currently included in the North of Tyne Formulary for other indications. Also some of the drugs requested for use in the treatment of gender dysphoria have possible physical contraindications associated with them and concerns were expressed as to who would be responsible for carrying out a physical evaluation of the patient. **Decision** – Approved. Clarification to be sought on the criteria by which psychiatrists choose the products used for the treatment of gender dysphoria in individual patients to ensure they are safe. A protocol to be drawn up which has been agreed with endocrinologists involved in the service.
NSAID review	√ See notes			In response to new targets for the reduction of prescribing of diclofenac, the APC was being asked to consider the formulary status of NSAIDs. Ibuprofen, diclofenac and naproxen are the preferred NSAIDs in the Formulary but no preference is given between the agents. **Decision** - The use of diclofenac for short term use for post operative pain to remain unchanged. For long term use ibuprofen low dose to be first line, followed by naproxen low dose, naproxen high dose and finally diclofenac as fourth line.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Venlafaxine MR tablets	√ See notes			The APC was asked to consider the possibility of discontinuing the prescribing of modified release formulations of venlafaxine. It was noted that significant savings could be made by switching from modified release to plain formulations but it was also acknowledged that there is still a small group of patients who may need to be prescribed a modified release formulation. Some savings could be realised by moving from modified release capsules to tablets. **Decision** – Some savings could be realised for PCTs by moving from modified release capsules to mr tablets however this would increase costs for secondary care. The formulary subcommittee was asked to work with NTW to develop guidance for prescribers to define the circumstances in which Venlafaxine mr preparations may be considered clinically appropriate. This will be supported through NTW medicines management committee.

July 2010