North of Tyne
Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 13th July 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
Alexander Dyker (AD)	Consultant Physician	NUTH
Rosie England (RE)	Head of Medicines Management	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
Dominic McDermott (DM) (for Bhavana Reddy)	Senior Pharmacist	RDTC
Peter McEvedy (PM)	GP representative from the PBC community North of Tyne	NHS NoT
Andy Reay (AR) (for Tim Donaldson)	Prescribing Interface Lead Pharmacist	NTWT
Alison Smith (AS)	Prescribing Adviser (Provider) – representing prison service	NNTCH
Simon Thomas (ST)	Consultant Clinical Pharmacologist	NUTH
Mritunjay Varma (MV)	Consultant Anaesthetist, Newcastle General Hospital	NUTH
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NECN
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Tim Donaldson	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Sue Gordon	Consultant in Public Health Medicine	NHS NoT
Mike Guy	Medical Director	NHS NoT
Bhavana Reddy	Acting Director of Pharmacy	RDTC

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

2010/37 Minutes of the meeting held on Tuesday 11th May 2010

These were accepted as a true record.

2010/38 Matters arising

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

No progress was reported on this item.

2010/27a Links between the APC and the North of Tyne guidelines group
Stephen Blair, the chair of the North of Tyne guidelines group, had been contacted to see how the APC could link with the group. Although the recent White Paper may affect any arrangement, an interim solution was put in place whereby the APC professional secretary would be added to the distribution list of the guidelines group. Any papers could then be circulated to APC members if appropriate.

2010/27d Pregabalin and amitriptyline in neuropathic pain management
It was reported that a drug company had sought further information on the committee's decision on this topic. A letter had been written to the company's representative, clarifying the decision making process and explaining that the APC did not normally publish detailed discussions held by the Formulary Sub-committee but only the final decisions made by the APC itself.

2010/30 Monitored dosage systems/compliance aids
A meeting to progress this issue is planned for the beginning of August.

2010/39 Appeal against previous decisions
No appeals had been received.

2010/40 Report from the Formulary Sub-committee

a) Minutes and recommendations from the meeting held on Tuesday 22nd June 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:

- Juvederm® Ultra 3 – although this was approved for use, it was emphasised that the procedure for which it is used is NOT available on the NHS.
- Nifedipine/Diltiazem – It was emphasised that new patients should be started on once daily preparations as defined in the Formulary and that twice daily preparations should not be prescribed. The relative costs of brands listed in the Formulary will be reviewed.
- Vitamin D guidelines – a draft guideline on Vitamin D deficiency had been submitted to the Formulary Sub-committee but had included products not on the Formulary. The authors of the guideline had been contacted by the sub-committee.
- Quinine – The MHRA had issued advice that quinine was not recommended to be routinely used in the treatment of nocturnal leg cramps and should only be considered when cramps cause regular disruption of sleep. After an initial trial of four weeks, treatment should be stopped if no benefit is gained. A suitable warning will be added to the Formulary.

b) Discontinuation of Mixtard® 30 insulin
Mixtard® 30 insulin is to be discontinued at the end of December 2010. It was felt by diabetologists that Humulin M3® was a suitable alternative although individual cases may differ and would be dealt with appropriately.

c) Formulary version 2.5 (June 2010)
This version of the Formulary is now available on the APC website.

2010/41 Report from the Shared Care Group (SCG)

a) Minutes of the meeting held on Wednesday 16th June 2009

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

- Criteria for traffic light classification of drugs – It was confirmed that these decisions are made by the APC guided by the Formulary Sub-committee. Helen Seymour had prepared a document, clarifying the process and criteria, which would be sent to the APC for discussion.
- Shared Care Guidelines and paediatric conditions - The general position was that the Shared Care Group looks at adult guidelines.

b) Dronedarone information leaflets for primary care

This leaflet was approved, subject to some minor amendments, and would be placed on the APC website in the section for Blue drug information leaflets. It was also confirmed that when drugs were classified as Blue, then the information leaflet should be written by the applicant as a condition of approval.

c) Removal of atypical antipsychotic shared care guideline

An information sheet is being developed for this group of products as they are now classified as Blue drugs for the conditions stated in the guideline. The shared care guideline will then be removed from the website.

d) Shared care guideline on methylphenidate in the treatment of ADHD in adults

Information warning about the use of illegal drugs and alcohol will not now be included in this shared care guideline (APC minute 2010/17b). Instead the guideline will be amended to include a statement referring the patient back to the consultant if they are misusing drugs or alcohol.

ACTION: AR to amend the guideline and send to DCo to place on the APC website.

e) Future of the Shared Care Group

A letter from HW had been circulated and was noted by the committee. In view of the recent White Paper, it was decided to defer discussion until the next meeting.

2010/42 Report from the Antimicrobial Chemotherapy Sub-Group

No meeting of this sub-group had been held.

2010/43 Prescribing of methotrexate

Following the receipt of correspondence querying the fact that many GPs limit Methotrexate prescriptions to one month, the committee discussed whether the current APC guideline should be changed. One suggestion had been to state that prescribing should be for a period that covers the patient's monitoring interval. It was felt that this would be difficult for GPs so it was decided not to change the current APC guideline.

DECISION: The APC guideline *'Prescribing of Methotrexate – September 2008'* would not be changed.
ACTION: DCa to write to the correspondent explaining the APC's position.

2010/44 Clopidogrel and proton pump inhibitors

In view of recent MHRA advice on clopidogrel and proton pump inhibitors, it was decided to revise the recently withdrawn APC guidance (APC minute 2010/31).

ACTION: IC to revise the recently withdrawn APC guideline on clopidogrel and PPIs and send to DCo to place on the APC website

2010/45 APC Annual report 2009-10

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.

2010/46 Documents previously circulated

These were noted as having been received.

The NECDAG approval of herceptin in combination therapy was queried both in terms of the cost per QALY and also the fact that the minutes noted that the meeting was not quorate.

SWi replied on behalf of NECDAG to these two points:

- Quorate - the meeting was missing a commissioner, so a recommendation to approve could be made on the day but financial approval could not be granted at the meeting. The group sought financial approval from the missing commissioner after the meeting who agreed to fund and confirm the recommendation to approve. This was done before the approval was made public ensuring compliance with NECDAG procedure.
- QALYS: The decision was made on consideration of evidence presented, by those committee members present and discussed with commissioners as described above.

SWi also stated that there is no set QALY limit used by NECDAG for 'end of life'. Evidence from NICE approvals suggests that it is around £50K but the criteria takes into account perceived value of life.

2010/47 Chair's action

Nothing to report.

2010/48 Any other business

a) North of Tyne Medicines Management QIPP project brief

RE gave a brief outline of this work, which is still in development, and highlighted four key areas:

- Optimising drug of choice
- Repeat prescribing management and reduction of waste
- Procurement of a range of products
- Local decision making processes

b) NETAG meeting

It was noted that NETAG had a meeting during the morning and that its decisions would be published shortly.

2010/49 Date and time of next meeting

The date of the next meeting is Tuesday 7th September 2010.

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

Signed: ..... **Date:** 7/9/10

vice **(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 13th July 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®		√ See Notes		Sterile alginate/ hydrocolloid dressing designed to combine the properties of both types of dressing with high absorbency. Initially requested with a view to it replacing Aquacel® in the Formulary. **Decision -** The application has been withdrawn by the Tissue Viability Group.
2) New Requests				
Dutasteride (Avodart®)		√		A 5-alpha reductase inhibitor requested for use in patients with moderate to severe symptoms, with larger prostates and elevated PSA levels. There have been previous applications requesting the inclusion of dutasteride in the Formulary which have been refused due to lack of supporting efficacy data. However, recently, the results from the 4 year CombAT study have been published and demonstrate the efficacy and tolerability of dutasteride. **Decision-** Not approved as the new evidence of efficacy in combination therapy is not strong enough to warrant its support.
Eslicarbazepine (Zebinix®)	√ B			A new voltage-gated sodium channel agonist that has been requested for use in the adjunctive treatment of partial epilepsy in those patients who have shown side effects to carbamazepine and who have shown failure to respond to alternative first line antiepileptic medication. **Decision**- Approved for use by specialists only in those patients for whom intolerance of carbamazepine is a major concern and where use of this agent is more cost effective than alternatives available. It was given blue drug status and an information leaflet will be prepared by the applicant.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Ibuprofen IV (Pedea®)	√			Requested to be used for the closure of patent ductus arteriosus in neonates. There has been a national shortage of IV indomethacin and this is the only licensed alternative available. **Decision-** Approved for use in the treatment of patent ductus arteriosus but only when there is a shortage of indomethacin. If required to replace IV indomethacin permanently, then a stronger case would be needed to be made.
Juvederm® Ultra 3	√			A hyaluronic acid product that is in widespread use in the cosmetic sector. Requested for use in the correction of moderate to severe facial wrinkles and folds by consultants treating private patients on NHS premises. Hyaluronic acid based fillers are biocompatible, safe, effective and well tolerated. Juvederm® ultra 3 contains a local anaesthetic, and this will allow a more pleasant administration of an injection for individual patients. At present, the only preparation available on the Formulary is Restylane® but this does not contain a local anaesthetic. **Decision -** Approved for use. **Note: the procedure for which Juvederm® ultra is used is NOT available on the NHS.**
Nicotinic Acid and Laropiprant (Tredaptive®)	√ See Notes			A combination drug that has been requested: • For secondary prevention in people with CVD who are unable to tolerate existing treatments. • As a cholesterol lowering agent in patients with heterozygous familial hypercholesterolemia who are intolerant to existing treatment. • As a triglyceride lowering treatment for patients with severe hypertriglyceridaemia. Niaspan® is the current nicotinic acid formulation in the Formulary, however there have been continuous supply issues with Niaspan®, and the major problem with Niaspan® is cutaneous flushing leading to discontinuation of treatment in a large group of patients. Tredaptive® has a specific flushing pathway inhibitor, laropiprant, and studies have demonstrated that Tredaptive® has reduced discontinuation rates by half. It does not appear to be associated with any additional adverse effects, and has been demonstrated to have a therapeutic advantage over Niaspan® and is a cheaper alternative. **Decision -** Approved for use in line with NICE GC71 and as a single agent to replace Niaspan®. Niaspan® to be removed from the Formulary.
Testosterone Transdermal Patches (Intrinsa®)		√		Formulation of testosterone requested for the treatment of hypoactive sexual desire in women. This was rejected by the APC on 22nd May 2008 due to lack of efficacy data. **Decision -** Not approved as no sufficient new data has been published.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
3) New formulations & extensions to use				
Ferric Carboxymaltose Ferrinject®	√			Parenteral iron preparation that is quicker and easier to administer than other parenteral iron products and is less likely to cause anaphylactic reactions, avoiding the need for test doses. Use may reduce the number of hospital attendances for some patients and the time patients need to spend at the hospital. Ferrinject® was approved by the APC on 18th September 2008 for limited use in locally agreed situations where its use is clinically and financially sensible. This restriction has been interpreted in different ways and it has been requested, to avoid ambiguity, that this be removed and that Ferrinject® be freely available for use by renal physicians and haematologists. **Decision** – Approved for use by renal physicians, gastroenterologists and haematologists.
Memantine for the treatment of congenital and acquired nystagmus.	√			Requested for the treatment of congenital and acquired nystagmus in patients who are intolerant to gabapentin. At present there is no alternative preparation available in the Formulary to patients who are intolerant to gabapentin. Memantine is considerably more expensive than gabapentin. **Decision -** Approved for use as a last line drug, after other alternatives have been considered, in the treatment of congenital and acquired nystagmus.
4) Products considered by NECDAG				
Trastuzumab (Herceptin®) with cisplatin and fluorouracil/ capecitabine	√ R			Approved for first line treatment of metastatic or locally advanced inoperable gastric cancers (including gastric junction) which over express HER-II when measured by IHC+++ or IHC++ and FISH+. Trastuzumab is given in combination with chemotherapy (cisplatin & fluorouracil/capecitabine). Up to 6 cycles of chemotherapy should be given, and trastuzumab should continue until disease progression.
5) Products considered by NETAG				
No products had been considered by NETAG				
6) Appeals against earlier decisions by the APC				
No appeals were considered by the APC				

Product	Decision: Approved	Decision: Refused	Decision: Deferred	Comments/notes
7) Miscellaneous decisions by the APC				
Dronedarone (Multaq®)	√			A class III antiarrhythmic drug approved by the APC on 11th may 2010 for use by cardio electro physiologists for use in those patients who are unsuitable or not tolerant of amiodarone. Cardiologists in Northumbria Acute Trust had expressed concerns over the decision to restrict its use to cardio-electrophysiologists. **Decision** – Restriction removed. Treatment should now be initiated by cardiologists.
Dyes, Patent Blue and Methylthioninium Chloride	√ See Notes			These were reviewed following information obtained highlighting the risk of anaphylactic reactions with patent blue. This 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 MHRA Drug Safety Bulletin. Comments were received from surgeons using patent blue. It is specifically being used for sentinel lymph node biopsies and literature recommends patent blue as the dye of choice. **Decision –** Methylthioninium chloride and Patent Blue to remain in the Formulary, but Patent Blue is restricted to use in sentinel lymph node biopsies (although their listing has been omitted in error). This means that there is no change to the range of dyes in the Formulary.
Hormone replacement therapy	√ **Evorel® Sequi** **Premique® Low Dose** **Climaval®**	√ **Utrogestan®** **(See notes)**		This section of the Formulary had been reviewed by the Formulary Sub-committee with specific evaluations being prepared for Utrogestan®, Evorel® Sequi, and Premique® Low Dose. Utrogestan® - requested for use as a progesterone component of HRT to give a wider choice for the patient. Evorel ®Sequi - requested as a replacement for a discontinued product and the only sequential patch available. Premique® Low Dose - suggested for addition to the Formulary because it is lower in strength than Kliovance®, and it cheaper than Kliovance®, Premique® and Kliofem®. **Decision –** • **Utrogestan®** – Not approved. There was not sufficient evidence to support its advantages over products currently approved and a full application is to be made. • **Evorel® Sequi** - Approved • **Climaval®** – Approved as the first choice estradiol with Elleste® Solo and Progynova® as alternatives. **Premique® Low Dose** – Approved

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Mesalazine products	√ **Mesren® MR** **Asacol® MR** **Pentasa® sachets** (see notes)	√ **Mesavant® XL** (see notes) **Asacol® 800** **Olsalazine**		The comparative properties and costs of the different oral 5-aminosalicylate preparations, used in the management of inflammatory bowel disease, had been reviewed. Gastroenterologists across the North of Tyne were contacted and a consensus of their comments and opinions collated. **Decision** – • Mesren® MR approved as the first line treatment for all new patients • Asacol® MR to remain the treatment for existing patients. • Pentasa® sachets to be added to the Formulary for those patients who have difficulty in swallowing. • Mesavant® XL not approved for inclusion in the Formulary. • Olsalazine to be removed from the formulary. • Asacol® 800 – Not approved however a new application would need to be submitted to consider the case for inclusion in the Formulary.
Nifedipine/ Diltiazem	√ See notes			The Formulary Subcommittee had been asked to review the position regarding generic and brand prescribing of modified release formulations of the calcium channel blockers nifedipine and diltiazem. **Decision** - New patients should be started on once daily preparations as indicated in the Formulary. Twice daily preparations should no longer be prescribed. However, considering the Pharmaceutical Society guidelines, patients could remain on their current brand of diltiazem and nifedipine, but pharmacists can suggest a substitute to prescribers and this should be explained to the patient.

July 2010