North of Tyne
Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 10th May 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
Rosie England (RE)	Associate Director of Medicines Management	NHS NoT
Matt Grove (MGr)	Consultant Rheumatologist, NTGH	NHCT
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
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 D&T panel	NUTH

In Attendance

Debbie Matthews (DM) (for item 2011/29a)	Consultant Paediatric Endocrinologist, Royal Victoria Infirmary, Newcastle upon Tyne.	NUTH

Apologies

Sue Brent	Director of Pharmacy	RDTC
Sue Gordon	Executive Director of Public Health	NHS NoT
Mike Guy	Medical Director	NHS NoT
Janet Kelly	Nurse Clinical Manager	NNTCH
Zahra Irannejad	Head of Prescribing	NNTCH
Jayanta Sarma	Consultant Microbiologist, NTGH	NHCT

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

2011/27 Minutes of the meeting held on Tuesday 8th March 2011

Under item 2011/17b the note should be added that **Golimumab was approved because of the financially advantageous access scheme.**

Under 2011/21, monitored dosage systems, it should be noted that **a common**

assessment tool is being developed and all new patients needing an MDS will be assessed using this tool and given one, if required, before discharge from hospital i.e. they will not be discharged from hospital without one if needed. Otherwise the minutes were accepted as a true record.

2011/28 Matters arising

2011/08 Non-Formulary requests

RE and ZI were continuing to investigate ways in which Formulary compliance in primary care can be improved. This will be reported via the Medicines Management QIPP Sub-Group in future.

2011/12b Interim guidance on provision of oral nutritional support

These have now been superseded by the commissioning of dietetic teams in each of the PCO areas. Emerging GP commissioning consortia have been contacted directly by the dietetic teams to make them aware of the new service arrangements.

2011/21 Monitored dosage systems (MDS)/compliance aids

A document had been circulated detailing how MDS will be managed in the community setting. As noted in minute 2011/27, a common assessment tool is being developed and, once implemented, all new patients needing an MDS will be assessed using this tool and given one, if required, before discharge from hospital.

2011/22 NPC Diagnostic Tool review

It was reported that the New Product Application Form does provide a framework to ensure due consideration is consistently given to each application and its impact on both patients and the health economy. Some work is still needed to ensure that all sections of the form are completed before an application is considered. Also the criteria applied needs to be consistent across all of the APC's documentation such as guidelines and statements. A full report will be provided for the next meeting.

ACTION: RE to circulate a full report for consideration at the next meeting.

2011/25b IV Colloids

The applicants for these products have confirmed their continued support for their use despite the retraction of some papers used in the original applications. They felt that the use of IV colloids was sufficiently supported by other studies.

2011/29 Appeals against previous decisions

a) Growth hormone review (reviewed by APC on 8th March 2011)

Dr Debbie Matthews, Consultant Paediatric Endocrinologist, Royal Victoria Infirmary attended for this item. Dr Matthews, in presenting the appeal, made the following points:

- Growth hormone is essential to general well being (e.g. muscle strength and bone density), not just height.
- Patients treated with growth hormones receive treatment over many years and adherence to therapy is essential.
- Compliance is difficult to monitor and any measure or device that enhances compliance is desirable.
- The device chosen to deliver growth hormone should match the needs of the patient and carer.
- The current APC decision seemed at odds with NICE guidelines and compromised patient care.

Dr Matthews stated that the proposal from the paediatric endocrinologists was that patients should be directed towards Omnitrope®, the cheaper product, if there were no special circumstances.

The committee reviewed the data presented and the points raised for the appeal, noting in particular the intention by the paediatric endocrinologists to direct patients towards Omnitrope®, if there were no special circumstances. As this was more or less in line with the committee's original decision of 8th March 2011, it was decided that this should remain unchanged. In addition prescribing of growth hormone will be monitored by Newcastle upon Tyne Hospitals NHS FT to gauge the uptake of Omnitrope® as per the APC's decision. This would be reviewed by the committee at a later date. The committee also expressed the view that its original decision **was** in line with NICE guidance.

DECISION: Original decision unchanged. In addition prescribing of growth hormone will be monitored by Newcastle upon Tyne Hospitals NHS FT and reviewed by the committee at a later date.

b) Tacrolimus (reviewed by APC on 8th March 2011)

A letter and clinical criteria were received from Professor Manas, Consultant Hepatobiliary and Transplant Surgeon, Freeman Hospital. In the letter the following points were made:

- Concern was expressed in converting stable patients from Prograf® to Adoport®.
- The clinical team had no experience to date in using Adoport®.
- The clinical team agreed that it was acceptable to use Adoport® in *de novo* patients who were considered low risk.

The committee reviewed the documentation sent and the points raised, noting that the original APC decision had not been to convert stable patients from Prograf® to Adoport®, but from Prograf® to Advagraf®. This was in line with the clinical criteria presented and the original application. The committee also felt that there was no scientific reason why all new patients could not start treatment on Adoport®, but acknowledged that the clinical team needed a period of time to gain experience with this product. As a result the committee felt that its original decision should remain unchanged but in addition, over the first 3 months of the introduction of Adoport®, its use should be restricted to selected low risk patients (first transplants with 0 DR mismatch). This use should be extended to moderately high risk patients after this period, unless scientific evidence against such a move comes to light. It is anticipated that all de novo patients will receive Adoport® within 6 months of its introduction.

DECISION: Original decision unchanged. In addition, over the first 3 months of the introduction of Adoport®, it's use should be restricted to selected low risk patients (first transplants with 0 DR mismatch). This use should be extended to moderately high risk patients after this period, unless scientific evidence against such a move comes to light. It is anticipated that all de novo patients will receive Adoport® within 6 months of its introduction.

2011/30 Report from the Formulary Sub-committee

a) Minutes and recommendations from the meeting held on Thursday 14th April 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 points were highlighted:

- Saxagliptin – this would be first line treatment and used for new patients whilst sitagliptin would be kept for existing patients only and with a view to it being removed from the Formulary.
- ARBs review – Losartan to be first line and candesartan second line treatment for all new patients. Irbesartan and valsartan to be retained for use in existing patients only. The Medicines Management QIPP Sub-Group will develop a strategy to be implemented by medicines management teams in primary and secondary care across North of Tyne to facilitate change in practice.
- Romiplostim – Recently recommended by NICE for the treatment of adults with chronic immune (idiopathic) thrombocytopenia purpura (TAG 221).

DECISION: Approved for addition to the Formulary for use according to NICE guidelines.

It had been noted by the NPC that many decision making groups did not manage disinvestment in medicines as effectively as the managed entry of new medicines. In this regard, it was agreed that it would be beneficial if the Formulary only listed drugs that are approved for initiation within the North of Tyne area. It was recognised that some of those products listed above were good examples of products which could be removed for the Formulary with this new format. It was accepted that this would not be a straightforward process and would need excellent communication to users prior to and during any migration towards that format. It was agreed that the way this change should be managed required a lot more thought prior to implementation.

DCa noted that Dexrazoxane (Savene®), a product used in the management of extravasation, was not approved by the APC or NECDAG but had been used by some clinicians leading to some inconsistency in management of this condition across the North of Tyne. SWi stated that this would be picked up by NECDAG when the cancer network revisited its guidance on the Management of Extravasation.

b) Formulary version 3.0 (March 2011)
This version of the Formulary is now available on the APC website.

2011/31 Report from the Shared Care Group (SCG)
a) Minutes of the meeting held on Wednesday 16th March 2011
These were noted as having been received.

b) Shared care guideline on Vigabatrin
This was approved and would be placed on the APC website.

c) Updated shared care guideline on Lithium Therapy
At its meeting on 8th March 2011, the APC approved the use of Lithium in the treatment of cluster headaches. This guideline had been updated to include this indication. It 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, subject to some minor modifications, and would be placed on the APC website in the section for Blue drug information leaflets:
(a) Ivabradine
(b) Lanreotide and Octreotide

(c) Prucalopride

e) Dekristol® - Colecalciferol (Vitamin D_3) 20,000 unit capsules – information leaflet for primary care

HW agreed to check this leaflet (approved 11th January 2011) to see if it was still required in the light of Vitamin D guidelines which were about to be published.

ACTION: HW to check to see if the information leaflet for Dekristol® - Colecalciferol (Vitamin D_3) 20,000 unit capsules, was still needed.

f) Dronedarone - information leaflet for primary care

The committee considered this leaflet and the associated traffic light status of BLUE but felt that it was more appropriate for dronedarone to be classified as an AMBER drug. The leaflet was therefore not approved.

DECISION: Dronedarone was reclassified as an AMBER drug. It is therefore suitable for use under Shared Care arrangements. The information leaflet for primary care was not approved.

2011/32 Report from the Antimicrobial Chemotherapy Sub-Group

No meeting of this sub-group had been held.

2011/33 Report from the Medicines Management QIPP Sub-Group

The minutes of a meeting held on Tuesday 15th March 2011 were noted and the fact that this group is now a sub-group of the APC.

2011/34 Declaration of Interests

TD noted that the APC did not clearly define what was required at its meetings regarding Declarations of Interests. DCa stated that this was an important matter and will be picked up at the next meeting where a discussion on updating the APC's Terms of Reference was planned (see agenda item 2011/37).

2011/35 Documents previously circulated

These were noted as having been received and the following points noted:

a) NETAG decision on dabigatran (18th January 2011)

Concerns were expressed that this decision had been made before a detailed guideline had been developed. It was agreed that this would be fed back to NETAG as an issue.

ACTION: DCo to contact the Professional Secretary of NETAG and express the APC's concerns that the decision on the use of dabigatran had been made before a detailed guideline had been developed.

2011/36 Chair's action

2011/12a Use of clopidogrel in TIAs

DCa confirmed that the paper prepared by the North of Tyne stroke physicians (agenda item 2011/15[2011/12a]) had been approved by chair's action.

2011/37 Any other business

a) Diamorphine to Morphine switches

At a recent meeting of the Controlled Drugs Local Intelligence Network (LIN) it was mentioned that a North East Palliative Care Group was looking at developing a policy of switching prescribing from diamorphine to morphine. It was identified as essential that the APC was happy with any recommendations and the best way to influence the right decision being made was to ensure correct membership of the group developing the recommendations. It was noted that NW was organising a

task and finish group across North of Tyne to review palliative care drugs and that this would be a useful route in to deliver this requirement as the membership of the groups would most likely overlap.

b) APC Terms of Reference

In view of a variety of issues, including the development of GP commissioning consortia, the APC Terms of Reference would need to be reviewed. This will be progressed at the next meeting.

c) Erythropoietin shared care guideline

LW presented a shared care guideline document for erythropoietin that had been sent to a GP. It was confirmed that this was not a guideline that had been ratified by the APC. LW would discuss further with HW (chair of the Shared Care Group).

d) Professional Secretary of the APC

It was announced that DCo would be leaving Northumbria Healthcare NHS FT within the next few months to take up a post as Specialist Procurement Pharmacist for the North East. David was congratulated on his appointment and thanked for the excellent job he has done over the last few years as Professional Secretary of the APC. DCa stated that he would be replacing DCo's Formulary Pharmacist position within NHCFT but that it was unreasonable to expect anyone newly appointed to take on the role of Professional Secretary of the APC. It was acknowledged that it would be necessary for a replacement to be identified from the membership of the APC and this would be discussed at the next meeting.

2011/38 Date and time of next meeting

The date of the next meeting is Tuesday 12th July 2011.
Venue: Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park.

Signed: ..... **Date:** 12/7/11
(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 10th May 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				
Indacaterol (Onbrez Breezhaler®)		√		A novel rapid onset of action inhaled long acting β_2 agonist providing 24 hour bronchodilation at once daily dosing. Indacaterol may be clinically advantageous compared to twice daily preparations such as salmeterol and formoterol as compliance is often poor in patients with COPD. Indacaterol has an onset of action of 5 minutes, compared to tiotropium or salmeterol which have an onset of action of approx. 30 minutes. Indacaterol would be used as either a replacement for or as an add-on to tiotropium, and would be expected to replace salmeterol and formoterol. **Decision -** Not approved because patient numbers appear to be unrealistic and because there is no combination product available for stepping up treatment.
Octanate®	√ R			Haematologists had requested that a small amount of this plasma derived factor VIII product be stocked for use for patients who might be travelling. Octanate® is appropriate for use in patients with severe Haemophilia A and an inhibitor, and in whom there is agreement to undertake immune tolerance induction with a plasma derived product. The price of Octanate® has been fixed and is less than that of recombinant factor VIII products. **Decision** – Approved. The possibility of wider use of Octanate® was explored, however national guidance does not allow the first line use of plasma derived factor VIII in patients with severe Haemophilia A.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Paricalcitol capsules & 5mcg/ml injection (Zemplar®)	√ R			Requested for use for the treatment of secondary hyperparathyroidism in a limited number of patients with stage 5 CKD on haemodialysis or peritoneal dialysis because of restrictions associated with alfacalcidol and cinacalcet, the products currently included in the Formulary for this indication. Specialists propose to try patients on paricalcitol before cinacalcet on the grounds that it is cheaper and may reduce the need for treatment with cinacalcet, by preventing PTH levels from reaching 800mcg/l. When management of secondary hyperparathyroidism fails, removal of the parathyroid gland may be necessary and this is a complicated procedure that is associated with a lot of risks. Paricalcitol is approximately half the cost of the 60mg dose of cinacalcet and approximately half of the forty patients currently on cinacalcet are prescribed doses of between 60 and 180mg. **Decision -** Approved for use in patients with PTH levels <800mcg/l but whose treatment with alfacalcidol is restricted due to a high calcium level. Classified as a Red Drug. The level at which Paricalcitol use will be triggered will be identified by the Nephrologists.
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. An application was considered and refused by the APC at its meeting on 11th January 2011.However it was indicated that a new application could be considered should the warning on renal impairment be removed in the future. This warning has now been removed and saxagliptin is slightly cheaper than sitagliptin, the product currently approved for this indication. **Decision -** Approved. Saxagliptin to be first line treatment used for new patients. Sitagliptin to be kept for existing patients and to be eventually removed from the Formulary.
Triamcinolone, nystatin, neomycin, gramicidin ointment (Tri-adcortyl®) (Unlicensed)	√			Triadcortyl® ointment was previously included in the North of Tyne Formulary for the treatment of otitis externa but was discontinued in 2009 for commercial reasons. An unlicensed formulation has become available again. Triadcortyl® ointment is considerably more expensive than the preparations currently included in the Formulary for this indication but has the advantage that it contains an antifungal agent. There is no licensed alternative available. **Decision -** Approved. To be included in the North of Tyne Formulary for the treatment of otitis externa in those patients who have ear canal stenosis or who have failed to respond to other first and second line treatments.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
3) New formulations & extensions to use				
Ivabradine tablets (Procoralan®)	√ B			Following a recommendation from the North of Tyne Heart Failure Guideline Group, a request was made to extend the approval for ivabradine to include symptomatic patients who have had an admission with heart failure within the last 12 months, if beta blockers have been optimised (or if patients are unable to tolerate beta blockers), heart rate is consistently 75 beats per minute or more at rest and in sinus rhythm and with a left ventricular ejection fraction of 35% or lower. It is not proposed that ivabradine should replace a beta blocker and only a relatively small number of patients would be eligible. By using ivabradine in this group of patients there will be significant reduction in hospital admissions for worsening heart failure and mortality. **Decision** – Approved. Ivabradine to be initiated and reviewed by specialists. Dr. Skinner will prepare an information sheet which will be updated when the product licence is changed.
Sevelamer Carbonate tablets and powder for oral suspension (Renvela®)	√			Requested for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis; and for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus ≥1.78mmol/l. Studies have demonstrated that it is equivalent to sevelamer hydrochloride, and it has been requested to replace sevelamer hydrochloride on the grounds that it has the advantage that it has an extended licence to non-dialysis patients whereas sevelamer hydrochloride does not. It can be administered less frequently which is useful to patients because of its unpleasant taste and useful for patients who can not swallow tablets. **Decision -** Approved for the indications requested. Patients currently prescribed sevelamer hydrochloride should be switched to sevelamer carbonate unless specialists have good reason not to change.
Spironolactone	√			A request to extend the approved indications for Spironolactone, was considered, to include • Patients with milder heart failure if they have other high risk features It was noted that Spironolactone is significantly cheaper than eplerenone. The NoT Heart Failure Guidelines 2011 have recently been reviewed. Whilst there are no large trials examining spironolactone in mild heart failure and in post MI, the Guideline Group felt that this represents a class effect of the aldosterone antagonists. Eplerenone may be used in patients who are unable to tolerate the estrogenic side effects of spironolactone. **Decision** – Approved. The approved indications for Spironolactone to be extended.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Tisseel® Ready Mix		√ See Notes		Requested for the 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 to Use is deep frozen and requires minimal preparation. There is reduced preparation time involved when using 2ml & 4ml packs. Studies have shown that Tisseel is at least as effective as staples, tacks or sutures in mesh fixation during the repair of inguinal or femoral hernia. The manufacturers of Tisseel® are offering a 17.6% discount which makes it the same price as the existing version of Tisseel®. **Decision -** Not approved. Tisseel® products not to be used in mesh fixation in hernia repairs. The proposal to replace Tisseel® Lyo with Tisseel® Ready Mix (for licensed indications excluding mesh fixation) to be deferred pending a review of fibrin sealants at which consensus will be sought from surgeons as to whether Tisseel® Ready Mix should be available instead of Tisseel® Lyo.
4) Products considered by NECDAG				
Azacitidine (Vidaza®)	√ R			Indicated for intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS). Approved by NECDAG from ICDF funding on 06.10.2010 for licensed indication only. Now approved by NICE so no longer funded from the Cancer Drug Fund.
Gemcitabine plus capecitabine (GEMCAP)		√		Proposed for a non-licensed use in patients with advanced pancreatic cancer. Rejected on the grounds of lack of clinical evidence. Not considered for the Cancer Drugs Fund.
5) Products considered by NETAG				
Bevacizumab (Avastin®)		√		NETAG considered the use of bevacizumab (Avastin®) outside of its product license in the management of neovascular glaucoma secondary to ischaemic central retinal vein occlusion. **Decision** - Not recommended for use within NHS North East for the treatment of neovascular glaucoma.
Tolvaptan (Samsca®)		√		NETAG considered the use of tolvaptan within its licensed indication for the treatment of hyponatraemia due to the syndrome of inappropriate antidiuretic hormone secretion (SIADH). **Decision** - Not recommended for use within NHS North East for the treatment of hyponatraemia due to SIADH. The group considered that tolvaptan is unlikely to be cost-effective compared with existing treatment options. In addition, the group was concerned about the potential for unrestricted long-term treatment.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Verteporfin (Visudyne®)		√		NETAG considered the use of verteporfin (Visudyne®) with photo-dynamic therapy (PDT) outside of its product license for the treatment of chronic central serous chorioretinopathy (CSCR). **Decision** - Not recommended for use within NHS North East for the treatment of chronic CSCR. The group considered that the evidence base for verteporfin in chronic CSCR was still of an experimental nature and was not sufficient to support clinical use.
6) Appeals against earlier decisions by the APC				
Growth Hormone review		√ See notes		A review of growth hormone products was carried out by the APC at its meeting on 8th March 2011. **Decision - Original decision unchanged**. The committee reviewed the data presented and the points raised for the appeal, noting in particular the intention by the paediatric endocrinologists to direct patients towards Omnitrope®, if there were no special circumstances. As this was more or less in line with the committee's original decision of 8th March 2011, it was decided that this original decision should remain unchanged. In addition, prescribing of growth hormone will be monitored by Newcastle upon Tyne Hospitals NHS FT to gauge the uptake of Omnitrope® as per the APC's decision. This would be reviewed by the committee at a later date. The committee also expressed the view that its original decision **was** in line with NICE guidance.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Tacrolimus (Advagraf®)		√ See notes		At its meeting on 8th March 2011, the APC approved the use of Advagraf® in patients currently prescribed Prograf®, and Adoport® for *de novo* patients. A letter had been received from the transplant team noting several points of concern, namely: • Concern over the conversion of stable patients from Prograf® to Adoport®. • The lack of experience in the use of Adoport®. **Decision - Original decision unchanged**. The committee reviewed the documentation sent and the points raised, noting that the original APC decision had not been to convert stable patients from Prograf® to Adoport®, but from Prograf® to Advagraf®. This was in line with the clinical criteria presented and the original application. The committee also felt that there was no scientific reason why all new patients could not start treatment on Adoport®, but acknowledged that the clinical team needed a period of time to gain experience with this product. As a result the committee felt that its original decision should remain unchanged but that in addition, over the first 3 months of the introduction of Adoport®, its use should be restricted to selected low risk patients (first transplants with 0 DR mismatch). This use should be extended to moderately high risk patients after this period, unless scientific evidence against such a move comes to light. It is anticipated that all de novo patients will receive Adoport® within 6 months of its introduction.
7) Miscellaneous decisions by the APC				
Angiotensin II Receptor Antagonists (ARBs) review	See Notes			The FSC reviewed ARBs with a view to rationalising the Formulary. Candesartan is currently the first choice ARB with irbesartan, valsartan and losartan offered as alternatives. Irbesartan was added as a cheaper and slightly more effective alternative to losartan because it does not require dose adjustments in patients with renal or hepatic impairment. Candesartan was added on the grounds that it is considerably cheaper and more cost effective than losartan in the treatment of hypertension. Generic losartan is now available and has prompted a review of the ARBs currently included in the NoT Formulary. **Decision -** Losartan to be the 1st line ARB for all new patients. Candesartan to be a 2nd line in all new patients. Irbesartan and valsartan to be retained for use in existing patients only.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Artesunate (anti - malarial treatment) (unlicensed)	√ R			The Dept of Tropical and Infectious Diseases has requested that artesunate be added to the Formulary for the treatment of severe P. falciparum malaria, as per WHO recommendations. Artensuate is unlicensed and WHO recommends artensuate in preference to quinine in adult patients, whereas in children either artensuate or quinine is recommended. It is considered to be safer than other treatments for malaria. **Decision -** Approved
Budesonide - discontinuation of Pulmicort® (budesonide) CFC-free inhalers/ nebuhaler spacer		See Notes		Pulmicort® CFC-free inhalers and nebuhaler® spacer have been discontinued. **Decision -** These products will be removed from the NoT Formulary.
Dexamphetamine- for narcolepsy	√ R>30mg B<30mg			Dexamphetamine is one of only two licensed available treatments for narcolepsy, the other being modafanil. The safety data for low dose dexamphetamine is relatively good. It is not used in patients with established uncontrolled hypertension, significant heart disease and patients over 65 years of age. Dexamphetamine is currently prescribed by a neurologist for use in narcolepsy in a small number of patients. The proposal is to follow up prescribing in primary care in doses not exceeding 30mg. **Decision -** The conventional use of dexamphetamine to be included in the Formulary. Doses less than 30mg have blue drug status and may be prescribed in primary care; doses over 30mg will continue to be prescribed and reviewed by hospital specialists.
Dronedarone	√ A			There has been a recent MHRA alert for Dronaderone, and its association with severe liver injury. Patients now require LFTs prior to treatment, on a monthly basis for six months, at months 9 and 12, and periodically thereafter. Originally a BLUE drug there had been discussion as to the most appropriate classification of this product to take into account the new monitoring requirements. **Decision** - The traffic light status of dronedarone is now AMBER. It is therefore suitable for use under Shared Care arrangements.
Memantine for Alzheimers disease	√			NICE has recently published new guidance for drugs in Alzheimer's disease (TAG 217). Memantine is not currently included in the NoT Formulary for the treatment of Alzheimer's disease, however memantine is now recommended as an option for managing moderate Alzheimer's disease for people who can not take AChE inhibitors, and as an option for managing severe Alzheimer's disease. **Decision** - Memantine to be included in the Formulary for the indications recommended by NICE. The Shared Care guideline to be amended by Andy Reay on behalf of the Shared Care Group.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Menotrophin multidose pens (Menopur®)	√ R			New formulations that have been requested for inclusion in the Formulary. **Decision -** Approved for inclusion in the Formulary.
Omalizumab 75mg and 150mg prefilled syringes	√ R			New formulations that have been requested for inclusion in the Formulary. The price is equivalent per mg to the vial. These are safer to administer than vials and using the new 75mg syringe for lower doses would save wastage from using a 150mg vial. **Decision** – Approved for inclusion in the Formulary.
Oxybutynin - discontinuation of Ditropan® Elixir	See Notes			Ditropan® Elixir (oxybutynin 2.5mg in 5ml) has been discontinued, but specialists in the Paediatric Department do not wish to use the available unlicensed formulation from Rosemont as it contains polyethylene glycol (PEG). Paediatricians historically avoid the use of PEG in children. For this reason it has been suggested that children requiring oxybutynin will receive tablets which will be crushed and dissolved in a known volume of water. **Decision** – Approved. Specialists in the paediatric department to produce a general information sheet on crushing tablets.
Romiplostim	√ R			Recently recommended in NICE TAG 221 for the treatment of adults with chronic immune (idiopathic) thrombocytopenia purpura. **Decision** – Approved for addition to the Formulary for use according to NICE guidelines.

May 2011