The NHS in Newcastle, North Tyneside and Northumberland

North of Tyne Area Prescribing Committee

ANNUAL REPORT April 2009 to March 2010

Executive Summary

The APC continued its work of facilitating clinical decision making across the North of Tyne. 100 non-cancer products were reviewed and 85% of all products reviewed were approved. The rest were either rejected or deferred.
The North of Tyne Formulary was updated regularly and available on the APC's website for public scrutiny along with minutes of meetings and decision summaries. The committee continued to regularly look at NICE and SMC decisions as well as reviewing newly licensed drugs and formulations.
A review was started of the clinical decision making process using a handbook and diagnostic toolkit from the National Prescribing Centre. This was to ensure that the committee operated in the most effective and efficient way.

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Introduction

The North of Tyne Area Prescribing Committee (APC) was established in January 2007 with the aim of facilitating a cross-organisational approach to medicines management, clinical decision making and related commissioning issues which affect primary care, acute hospitals, mental health, learning disabilities and social care. This report has been compiled to inform participating organisations of the Committee's activities for the 12 months up to the end of March 2010. The report includes the outcomes of new drug requests, membership details, attendance figures and other relevant/significant developments, areas of interest and involvement.

Membership

The Area Prescribing Committee (APC) serves the following participating organisations:

- Newcastle Primary Care Trust (NPCT)
- Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH)
- North Tyneside Primary Care Trust (NTPCT)
- Northumberland Care Trust (NCT)
- Northumberland, Tyne and Wear NHS Foundation Trust (NTWT)
- Northumbria Health Care NHS Foundation Trust (NHCT)

Membership of the committee comes from a wide variety of professional, clinical, educational, management, commissioning and organisational backgrounds.

Attendance figures

Between April 2009 and March 2010 there have been 6 meetings of the APC. The table below describes the attendance figures for members of the Committee.

Name	Job Title	Organisation	Attendance
David Campbell	Chief Pharmacist/Clinical Director for Medicines Management (Chair)	NHCT	5
Ian Campbell	Assistant Director of Pharmacy	NUTH	6
David Cook	Lead Clinical Pharmacist Procurement and Formulary	NHCT	6
Barry Corbett (for Tim Donaldson)	Chief Pharmacist and Associate Director of Medicines Management	NTWT	1
Tim Donaldson	Head of Pharmacy Clinical Governance	NTWT	3
Alexander Dyker	Consultant Physician	NUTH	2
Neil Frankland (for Rosie England)	Medicines Management Advisor	NHS NoT	1
Rosie England	Head of medicines Management	NHS NoT	3
Sue Gordon	Consultant in Public Health Medicine	NCT	5
Matt Grove	Consultant Rheumatologist, NTGH	NHCT	4
Mike Guy	Medical Director	NHS NoT	3
Mike Hannon	Community Pharmacist/North of Tyne PEC	NHS NoT	2
William Horsley (for Bhavana Reddy)	Senior Pharmacist Medicines Management	RDTC	1
Zahra Irannejad	Head of Prescribing	NNTCH	4
Janet Kelly	Nurse Clinical Manager	NNTCH	3
Kirsty Macfarlane *(Left the committee July 2009)*	Principal Pharmacist, Medicines Management	RDTC	1
Dominic McDermott (for Bhavana Reddy)	Senior Pharmacist	RDTC	1
Peter McEvedy	GP representative from the PBC community North of Tyne	NHS NoT	6
Andy Reay (for Tim Donaldson)	Prescribing Interface Lead Pharmacist	NTWT	1
Bhavana Reddy *(Joined the committee September 2009)*	Acting Director of Pharmacy	RDTC	0
Jayanta Sarma	Consultant Microbiologist, NTGH	NHCT	1
Helen Seymour (for Rosie England)	Medicines Management Advisor	NHS NoT	2
Alison Smith (for Zahra Irannejad)	Prescribing Advisor (Provider) – representing prison service	NNTCH	2
Caroline Sprake *(Left the committee July 2009)*	GP, PBC representative for North Tyneside	NHS NoT	0
Simon Thomas	Consultant Clinical Pharmacologist	NUTH	3
Glyn Trueman	Formulary Pharmacist	NUTH	6
Mritunjay Varma	Consultant Anaesthetist, NGH	NUTH	3
Neil Watson	Clinical Director of Pharmacy and Medicines Management	NUTH	4
Sue White (for Bhavana Reddy)	Acting Head of Prescribing Support	RTDC	1
Trevor White	GP, Chair of North of Tyne PBC Forum	NHS NoT	0
Steve Williamson	Consultant Pharmacist in Cancer services	NECN	4
Hilary Wynne	Consultant Physician/Chair of NUTH D&T Panel	NUTH	5

Glossary for organisations not listed on page 1

NECN	North of England Cancer Network
NHS NoT	NHS North of Tyne
NNTCH	Newcastle, North Tyneside Community Health Services
RDTC	Regional Drugs and Therapeutics Centre

Sub groups and committees

Various sub groups/committees exist to carry out specific programmes of work for the main committee. These include:

- **Formulary Sub-Committee –** This considers new product applications and leads the development of the shared formulary. Recommendations to approve, defer or reject applications, with summaries of evidence, are presented to the APC.

- **Shared Care Group -** This looks at the development of Shared Care Guidelines and associated issues.

- **Antimicrobial Chemotherapy Sub-group –** This looks at sharing good practice with regard to antimicrobial chemotherapy as well as develops, reviews and maintains antibiotic guidelines for use in both primary and secondary care settings.

Committee Officers

The tenure of committee officers came to an end in January 2010 and new officers took up their posts from this date. The following is a list of officers to the committee and its main sub groups/committees and officers before and after January 2010:

	Before January 2010	**After January 2010**
APC – Chair	David Campbell	David Campbell
APC – Vice Chair 1	Simon Thomas	Simon Thomas
APC – Vice Chair 2	Mike Guy (or deputy)	Rosie England
APC – Vice Chair 3	Hilary Wynne	Hilary Wynne
APC – Professional Secretary	David Cook	David Cook
Formulary sub-committee – Chair	Simon Thomas	Simon Thomas
Formulary sub-committee – Vice Chair 1	Alexander Dyker	Alexander Dyker
Formulary sub-committee – Vice Chair 2	Zahra Irannejad	Zahra Irannejad
Formulary sub-committee – Professional Secretary	Glyn Trueman	Ian Campbell (on a temporary basis)
Shared Care Group – Chair	Hilary Wynne	Hilary Wynne
Shared Care Group – Vice Chair	Richard Copeland	Helen Seymour
Shared Care Group – Professional Secretary	Tim Donaldson	Andy Reay
Shared Care Group – Technical Officer	Glyn Trueman	----------

Committee's activities/achievements

During the period from April 2009 to March 2010 the committee carried out the following key activities:

- **Formulary**
    - Work continued on the development and updating of the North of Tyne Formulary. Regular reviews of BNF sections will be undertaken to ensure the document remains up to date.

- **New drug applications**
    - Applications to have new drugs or formulations added to the formulary continued to be a large part of the committee's work. These were made on a

specific application form. Details of these applications and the committee's decisions are noted in **appendix 1** but in summary:

- 119 products were reviewed
- 101 (84.9%) of these were approved for use
- 14 (11.8%) were rejected for use
- 4 (3.3%) were deferred
- Also 19 were initially considered by the cancer network and 5 by the North East Treatment Advisory Group
- 3 appeals were made against decisions by the committee. Two decisions were unchanged and one was changed.

- **Communication**
  - The committee continued to publish details of its meetings and decisions, the North of Tyne Formulary, finalised Shared Care Guidelines and information leaflets for primary care and other statements and guidelines for both healthcare professionals and members of the public on its website: www.northoftyneapc.nhs.uk .

- **Shared Care**
  - Shared Care Guidelines were developed by the Shared Care Group. To date officially agreed guidelines include:
    - Atypical antipsychotics - February 06
    - The use of Donepezil, Galantamine and Rivastigmine in the treatment of dementia - May 2007
    - Immunosuppressive Treatment Following Renal Transplantation SCG (ratified March 2010)
    - Lithium therapy – updated November 2008
    - Methylphenidate for children and young people (updated) - March 2010
    - Naltrexone in Learning Disabilities - July 2009
    - High dose Venlafaxine in the treatment of depression – January 2008
  - Leaflets were developed to provide information to primary care professionals on drugs classified as BLUE under the 'traffic light' system. As at March 2010 the only ratified leaflet is for Melatonin.

- **Newly licensed drugs and formulations**
  - At each meeting the committee continued to review a list of drugs and formulations which had been newly licensed since the previous meeting. This included any formulary drug which had received a license for a new indication.

- **NICE and SMC**
  - The committee regularly looked at both NICE appraisals/guidance and SMC decisions to ensure that its own decisions and work plans are robust.

- **Benchmarking of clinical decision making process**
  - A working group started a review of the way decision making about medicines is carried out North of Tyne and sought to map out a whole system process, using a handbook and diagnostic toolkit from the National Prescribing Centre. One early outcome of this review resulted in the introduction of a form which requires committee members to declare any interests.

- **Unlicensed medicines**
  - A statement was issued providing some guiding principles on the prescribing of unlicensed medicines.

Summary

The North of Tyne Area Prescribing Committee continues to make good progress in bringing together clinical decision making across the North of Tyne health economy. It has had excellent primary and secondary care representation, has been well attended and delivers a significant improvement in governance associated with medicines use for all of the organisations involved.

Recommendation

The Boards/Professional Executive Committees (or other) of member organisations are requested to acknowledge the details of this report.

APPENDIX 1

Summary of APC Decisions April 09 to March 10

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 + date of decision			Comments / notes
	Approved	Refused	Deferred	
1) Requests Reconsidered or Deferred from 2008 - 2009				
Tetraspan®	√ 29 Sep 09			Approved for addition to the Formulary (as a replacement for pentastarches). The extent to which Tetraspan® and Volulyte® are used will be decided by each organisation, taking into account clinical factors and price.
Volulyte®	√ 29 Sep 09			Approved for addition to the Formulary (as a replacement for pentastarches). The extent to which Tetraspan® and Volulyte® are used will be decided by each organisation, taking into account clinical factors and price.
2) New Requests				
Ajmaline (Unlicensed)	√ R 12 Jan 10			Approved. Applicant to be asked to prepare a patient information leaflet.
Balanced Gelatine (Isoplex®)	√ 29 Sep 09			Approved for use in critical care patients and other situations where its perceived advantages are likely to be clinically important.
Biatain®Adhesive 10 x 10cm and 17cm contour dressings	√ 11 Mar 10			The 10 x 10cm dressings (with circular pad) and 17cm contour dressings approved for use. Other sizes of Biatain Adhesive have not been approved for use.
Botulinum A Toxin (Xeomin®)	√ 29 Sep 09			Approved.
Brinzolamide Eye Drops (Azopt®)	√ 04 Jun 09			Approved for the treatment of glaucoma. Consultation to take place on the possible removal of dorzolamide from the Formulary.
Dibotermin Alfa (InductOs®)	√ R 11 Mar 10			Dibotermin alfa approved for use in spinal fusion procedures: 1. In patients who have failed previous spinal fusion surgery. 2. Patients undergoing spinal fusion surgery where there is a very high risk of non-union. **It is not approved for use in anterior cervical spine surgery (one-off, non-formulary approval may be sought for individual patients).**
Doripenem (Doribax®)	√ R 26 Nov 09			Approved, but treatment should only be on the advice of microbiology or infectious disease physicians.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Dovobet® (Calcipotriol 50 micrograms, Betamethasone 0.5 mg)	√ 11 Mar 10			Approved for use in the treatment of stable plaque psoriasis.
Fluticasone furoate	√ 30 Jul 09			Approved for use in the treatment of symptoms of allergic rhinitis in patients aged six years and over. Beclometasone dipropionate nasal spray remains first choice product for treatment of allergic rhinitis. Consideration to be given to the possibility of removing triamcinolone acetonide nasal spray from the Formulary.
Gadoxetic acid (Primovist®)	√ 29 Sep 09			Approved for use in: • The assessment of hepatic vascular structures and biliary system of potential living, related liver donors. • The detection and characterisation of focal liver lesions using MRI, when standard imaging with other agents has been inconclusive. • The detection and characterisation of focal liver lesions which potentially communicate with the biliary system e.g. large liver cysts.
Ganfort® eye drops	√ 30 Jul 09			Approved for use as a 2nd or 3rd line agent in patients who are being treated for open angle glaucoma or ocular hypertension. Use to be reviewed if the cost of other prostaglandin/ beta-blocker preparations changes significantly.
Gentafleece®	√ 29 Sep 09			Approved.
Hyaluronic acid - Sub Q (Restylane Sub Q®)	√ 30 Jul 09			Approved for augmentation of orbital volume after removal of the eye in patients who have already had other volume enhancement surgery. Consultants to be asked to provide audit data and its use is to be reviewed after one year.
Hyaluronic acid - Perlane (Restylane Perlane®)	√ 30 Jul 09			Approved.
Indigo Carmine (Unlicensed)	√ R 26 Nov 09			Approved for use in colonoscopy.
KerraMax® Superabsorbent Dressing	√ 11 Mar 10			Approved. Tissue viability nurses to be consulted on the possibility of rationalising the range of highly absorbing dressings in the Formulary.
Liraglutide (Victoza®)		√ 26 Nov 09		Not approved. Potential advantages do not justify the additional costs.
Lymecycline) (Tetralysal 300®)	√ 12 Jan 10			Approved for use in the treatment of acne (and rosacea). Lymecycline is classified as a green drug and is for second-line use only. Consultation to take place on removing minocycline from the Formulary.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Methoxy polyethylene glycol-epoetin (Mircera®, CERA)	√ A 30 Jul 09			Approved for use, as an alternative to darbepoetin, eventual extent of use may be determined by local procurement arrangements.
Pivmecillinam (Selexid®)	√ 04 Jun 09			Approved for use in the treatment of acute uncomplicated cystitis caused by ESBL producing multi resistant coliform bacteria. Treatment should be initiated on the advice of a microbiologist.
Prasugrel (Efient®)	√ 30 Jul 09			Approved for use in accordance with draft NICE guidance and in other acute coronary syndrome patients (unstable angina or non ST segment elevation myocardial infarction) who have a true allergy to clopidogrel.
Prontosan® Irrigation Solution and Gel	√ 04 Jun 09			Approved. To be prescribed only on the advice of tissue viability specialists.
Ranazoline (Ranexa®)	√ 04 Jun 09			Approved for use in the treatment of angina in those patients for whom other treatments have been unsuccessful. Initial prescribing should be by a consultant cardiologist only.
Rephoren	√ 30 Jul 09			Approved for use as a phosphate binder in the treatment of hyperphosphataemia associated with chronic renal insufficiency in patients undergoing haemodialysis and peritoneal dialysis.
Rosuvastatin	√ B 29 Sep 09			Approved for limited use in the management of patients with familial hypercholesterolaemia who do not respond adequately or do not tolerate the maximum doses of other statins. Treatment should only be initiated by specialists working in lipid clinics. Classified as a Blue Drug. Use in primary care to be audited.
Somatropin (Omnitrope®)	√ 29 Sep 09			Approved for use.
Sugammadex	√ 30 Jul 09			Approved for use, subject to audits on its use being carried out at a local level.
Testosterone Propionate (Virormone®)	√ 12 Jan 10			Approved for use if the administration of Sustanon® 250 using a tuberculin syringe, with a needle suitable for intramuscular use, is not practicable.
Tocilizumab (Actemra®, RoActemra®)	√ R 12 Jan 10			Interim approval given for its requested use subject to consideration by NETAG...
Urgosorb®			√ 11Mar 10	Deferred pending the receipt of further information and discussion.
3) New Formulations & Extensions to Use				
N-Acetylcysteine (Acetylcysteine) 600mg tablets (Unlicensed)	√ B 29 Sep 09			Plain acetylcysteine 600mg tablets to be added to the Formulary (less expensive) and reclassified as a Blue drug.
Alprostadil (Caverject Dual Chamber® injections)	√ 04 Jun 09			Approved. The Caverject Dual Chamber® formulation of alprostadil to be added to the Formulary.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Babiven® (Unlicensed)	√ 26 Nov 09			Approved.
Caspofungin infusion	√ R 04 Jun 09			Approved. Use extended to secondary care. Remains as a 'Red' hospital only drug.
Cidofovir - for the prevention and treatment of CMV retinitis	√ 26 Nov 09			Approved. Approved indications for the use of cidofovir to be extended to include the prevention and treatment of CMV retinitis.
Darunavir (Prezista®) 400mg and 600mg tablets	√ R 04 Jun 09			Approved. Darunavir 400mg & 600mg to be added to the Formulary.
Desflurane (extension to use)	√ 29 Sep 09			Approved uses of desflurane extended to include: • Bariatric surgery. • Prolonged procedures over 2 hours e.g. oesophagectomy. • Surgery in the elderly where there are concerns of cognitive impairment • Major surgery in the elderly with or without cognitive dysfunction Subject to the following limitations: • Desflurane is not for use in day surgery unless the patient is morbidly obese. There is no role at present for its use in paediatrics or cardio-thoracic surgery. • Desflurane must be used in conjunction with low fresh gas flow. • Its use should be monitored over 12 months and audited.
Ethanol 20% eye drops (Unlicensed)	√ 12 Jan 10			Approved.
Extavia® (Recombinant interferon beta-1b)	√ R 30 Jul 09			Approved. To be added to the formulary as another brand of recombinant interferon beta-1b. For use alongside other formulations of beta interferon in accordance with the Department of Health's risk sharing scheme for drugs used to treat multiple sclerosis.
Ferric carboxymaltose (Ferinject®) use in paediatrics	√ 30 Jul 09 Children 14 years of age and over 29 Sep 09 Children under 14 years of age			Approved for the treatment of iron deficiency in children aged 14 years and over, where oral iron therapy is ineffective or cannot be used and its use is justified both clinically and economically. Approved for limited use in children under 14 years of age, but treatment should only be on the advice of a consultant, with the informed consent of the patient and/or his/her parents/ carers.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Galantamine liquid	√ R 26 Nov 09			Approved for short-term use in the management of hospital patients who are unable to swallow tablets/ capsules.
Gentamicin Sulphate powder	√ R 26 Nov 09			Approved for use in orthopaedic surgery.
Human Papilloma Virus Vaccine – Gardasil® Brand	√ 29 Sep 09			Approved for use in the management of patients with Fanconi anaemia.
Human Papilloma Virus vaccine (Gardasil® brand) – for use in children with HIV and some other blood born virus infections	√ 26 Nov 09			Approved. The approved indications for Gardasil® brand human papilloma virus vaccine to be extended to include use for the prevention of papilloma virus infection in children with HIV and some other blood born virus diseases.
Hyaluronic Acid injection – (Hydrafil Softline Max®)	√ 04 Jun 09			Approved for use as a replacement for Hylaform Plus®, which has been discontinued.
Ibandronic Acid			√ 12 Jan 10	Professor Francis to be advised that he should submit another new product application, accompanied by details of new evidence, if he wishes the possible use of oral ibandronic acid to be reconsidered.
Interferon beta-1a (Rebif®) multidose cartridges for use in Rebismart® device	√ R 30 Jul 09			Approved.
Linezolid oral suspension	√ R 04 Jun 09			Approved for use in those patients unable to swallow tablets.
Liquiband Optima®	√ 04 Jun 09			Approved for use.
Metformin - sachets	√ 30 Jul 09			Approved for use in patients who cannot swallow metformin tablets.
Midazolam oral suspension (unlicensed)	√ 30 Jul 09			Approved for use.
Nicotine Mini Lozenges (NiQuitin® Minis Lozenges)	√ 11Mar 10			NiQuitin® Minis Lozenges to be added to the range of nicotine replacement therapy products in the Formulary.
Octagam® 10% solution	√ 04 Jun 09			Approved for use.
Olanzapine Dispersible Tablets and Olanzapine Injection	√ A 11Mar 10			Olanzapine dispersible tablets and injection approved for use in the management of delirium in critical care patients. Treatment should only be initiated on the advice of specialists.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Prasugrel (Efient®)	√ 29 Sep 09			Requested for use in acute coronary syndrome patients with diabetes in accordance with updated NICE guidance and other indications in patients that are allergic to clopidogrel. The approved uses of prasugrel to be extended in line with the proposed NICE guidance and in other high risk patients who have a true allergy to clopidogrel. It should not be used for primary prevention.
Quetiapine modified release (Seroquel XL®)	√ A 11 Mar 10			Approved for use: 1. In patients who require an outside carer to administer their medicines, where its use would reduce the number of visits for administration. 2. Where rapid dose titration is considered important (e.g. by mental health trust crisis support teams) for example where its use might avoid the need to admit the patient to hospital. *If maintenance treatment with quetiapine is required, it should be with the conventional formulation (unless 1 above applies).*
Ratiograstim brand Filgrastim	√ 30 Jul 09			Ratiograstim should be approved for use. The switching of brands of filgrastim was considered an issue for each organisation.
Rivastigmine patches (Exelon®)	√ A 30 Jul 09			Approved for restricted use in patients for whom rivastigmine is an appropriate choice of treatment, in either of the following clinical circumstances: 1. For patients unable to tolerate treatment with oral rivastigmine due to nausea or vomiting. 2. For patients receiving treatment with an acetylcholinesterase inhibitor who are unable to take oral medication due to swallowing difficulties or being designated 'nil by mouth' (e.g. prior to surgery).
Rotigotine (Neupro®) transdermal patches – use in patients with restless leg syndrome	√ B 12 Jan 10			Approved. It should be prescribed only on the advice of a neurologist or a Movement Disorder specialist and information should be sent to the patient's GP.
Sildenafil for use in Raynaud's Syndrome	√ R 04 Jun 09			Approved. Dr Spickett to be contacted about the possibility of using tadalafil instead (lower cost).
Sodium Valproate (Episenta®)	√ 29 Sep 09			Prolonged release form of sodium valproate for once daily administration. Available in sachets and capsules which can be dispersed in soft food or a drink prior to administration. Approved for use in patients who have difficulty swallowing sodium valproate tablets.
Tadalafil for use in Raynaud's Syndrome	√ R 30 Jul 09			Approved, as a cheaper alternative to sildenafil.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Tamsulosin Hydrochloride extended release tablets (Flomaxtra XL®)		√ 26 Nov 09		Not approved. Advantages with regard to a slightly superior tolerability of Flomaxtra® XL not considered sufficient to justify its use given its higher cost.
Tisseel® Ready Mix		√ 11 Mar 10		Not approved.
Tobramycin nebules (Bramitob®)	√ 12 Jan 10			Approved for use as an alternative to Tobi®.
Triptorelin 3-monthly injection (Decapeptyl SR®)	√ 26 Nov 09			Approved.
Ubiquinone (Coenzyme Q10, Ubidecarenone) - unlicensed	√ 04 Jun 09			Approved for use in mitochondrial disorders. Also approved for use under specialist consultant supervision in the management of patients with severe hyperlipidaemia who are not tolerating statins due to myopathy. Use in statin induced myopathy is subject to initial prescribing being made by a consultant and data on its use being collected and audited.
Valganciclovir 250mg in 5ml oral solution (Valcyte®)	√ R 04 Jun 09			Approved.
4) Products Considered by NECDAG				
Aprepitant and Palonosetron	√ 26 Nov 09			Both are options for prevention of chemotherapy induced nausea and vomiting in selected patients and should be used in accordance with the cancer network's Antiemetic Policy.
Azacitadine (Vidaza®)		√ 04 Jun 09		Antimetabolite type cytotoxic drug, requested for the treatment of myelodysplasias. The cancer network was unable to approve as the economic case had not been demonstrated, but were keen to review the decision if new evidence becomes available.
Bevacizumab (Avastin®)		√ 04 Jun 09		Monoclonal antibody that inhibits vascular endothelial growth factor, requested for the treatment of metastatic breast cancer. The cancer network was unable to approve at this time as the economic case had not been demonstrated.
Bevacizumab (Avastin®)		√ 30 Jul 09		Requested for metastatic colorectal cancer patients with unresectable liver only metastases. Rejected due to lack of evidence of clinical benefit and lack of evidence of cost effectiveness.
Bortezomib (Velcade®)	√ R 30 Jul 09			Approved for first line therapy for multiple myeloma patients who have renal failure requiring haemodialysis.
Capecitabine with Irinotecan (CAPIRI)	√ R 12 Jan 10			Approved for the treatment of metastatic colorectal cancer.
Cetuximab (Erbitux®)	√ R 12 Jan 10			Approved for the first-line treatment of metastatic colorectal cancer in combination with 5-FU, folinic acid and oxaliplatin (FOLFOX) when certain criteria are met.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Cetuximab (Erbitux®)	√ R 12 Jan 10			Approved as single agent third-line treatment for patients with K-RAS wild-type metastatic colorectal cancer who have failed treatment with irinotecan and / or oxaliplatin-based chemotherapy.
Cisplatin and Etoposide	√ R 30 Jul 09			Approved for induction concurrent chemoradiotherapy to superior sulcus carcinomas of lung – where possible, prior to surgery.
Cisplatin and Gemcitabine	√ R 26 Nov 09			Standard regimen for palliative treatment for biliary tract cancers now changed to cisplatin and gemcitabine.
Deferasirox (Exjade®)	√ 30 Jul 09			Approved for iron chelation for patients with myelodysplastic syndromes (MDS) - (as per NECN Haematology Group Guidelines)
Degarelix (Firmagon®)	√ R 11 Mar 10			Approved for first line treatment of advanced hormone-dependent prostate cancer with at least one of the following: • PSA > 50mg/l at presentation • Urether obstruction • Symptoms of spinal cord compression The approval is conditional on the manufacturer giving either a discount or a rebate against the cost of degarelix equivalent to the cost of goserelin.
Gemcitabine	√ R 26 Nov 09			Standard chemotherapy regimen for adjuvant pancreatic cancer now changed to gemcitabine.
Lapatinib		√ 26 Nov 09		Requested for advanced or metastatic breast cancer whose tumours over express ErbB2 (HER2) in patients with progressive disease following prior therapy, which include anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting. The cancer network was unable to approve as the cost effectiveness case had not been met.
Plerixafor (Mozobil®)	√ R 26 Nov 09			Requested for stem cell mobilization in the management of patients failing first mobilization with multiple myeloma and lymphoma.
Rituximab (Mabthera®)	√ R 04 Jun 09			Anti CD20 monoclonal antibody, approved for use as 1st line treatment of chronic lymphocytic leukaemia in combination with fludarabine and cyclophosphamide chemotherapy.
Rituximab	√ R 26 Nov 09			Requested, in combination with fludarabine and cyclophosphamide, for patients with CLL – Binet stage B or C, as treatment of relapsed disease. Previously approved for 1st line treatment of CLL.
Streptozocin	√ R 26 Nov 09			Requested for use with capecitabine as treatment for the management of inoperable neuroendocrine tumours (NET).
Zevalin®		√ 30 Jul 09		Requested in the treatment of non-Hodgkin's lymphoma. The cancer network did not feel that there was currently sufficient clinical evidence to support use.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
5) Products considered by NETAG				
Agomelatine (Valdoxan®)	√ R 26 Nov 09			Approved for the treatment of depression only following an adequate trial (as described by NICE and as stated in the BNF) of at least three alternative antidepressant drugs at maximally tolerated doses. Prescribing and monitoring should be initiated by, and remain wholly under the supervision of, specialist mental health physicians.
Deferasirox (Exjade®)			√ 11 Mar 10	An appraisal of deferasirox was conducted for the treatment of chronic iron overload within its licensed indications. Deferasirox is an orphan drug that has been available in the UK for this indication since 2007. A decision was deferred pending more accurate estimation of the actual cost impact for NHS North East.
Fentanyl – novel oramucosal (Abstral®, Effentora®)and nasal (Instanyl®) forms		√ 26 Nov 09		Appraisal conducted regarding novel fentanyl products within their licensed indication for the treatment of breakthrough cancer pain. The novel fentanyl products Abstral®, Effentora® and Instanyl® are not approved for use within NHS North East.
Sodium Oxybate (Xyrem®)		√ 11 Mar 10		An appraisal of sodium oxybate was conducted for use within its licensed indications for the treatment of narcolepsy and cataplexy. Sodium oxybate is an orphan drug that has been available in the UK for this indication since 2006. Sodium oxybate (Xyrem®) is not approved for use within NHS North East.
Ulipristal (ellaOne®)	√ 26 Nov 09			Ulipristal (ellaOne®) recommended as the preferred drug treatment option for post-coital contraception for patients who present between 72 and 120 hours following unprotected intercourse. Levonorgestrel is still recommended for patients who present at up to 72 hours following unprotected intercourse.
6) Appeals against earlier decisions by the APC				

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Mazindol (unlicensed)		√ 30 Jul 09		This was initially refused by the APC at its meeting on 4th June 2009 for use in the treatment of narcolepsy.. Not approved. The committee felt that its original decision not to approve the addition of this drug to the Formulary should stand for the time being. However the committee felt that if the following information could be provided, then it would would look favourably on the use of mazindol: • An application to the Formulary Sub-committee for the use of methylphenidate in narcolepsy. Being a licensed product would give such an application an advantage over an unlicensed product such as mazindol. • An algorithm of therapeutic options for patients, indicating the placement of each product in the treatment pathway. • Details of ongoing monitoring requirements for patients. Written information that might be given to patients about products prescribed and their consent to follow-up.
Methylphenidate modified release (Equasym XL®, Medikinet XL® & Concerta XL® 27mg tablets)	Concerta XL® A 12 Jan 10 Equasym XL A 11 Mar 10	Medikinet XL 11 Mar 10		At a meeting of the APC on 26th November 2009 Equasym XL® was approved, Medikinet XL® was not approved and consultation was to take place on the possible removal of Concerta XL® from the Formulary. An appeal was heard on 12th January 2010. The committee discussed the points raised for the appeal, noting in particular the duration of action of the various brands, and revised its earlier decision as follows: **Concerta XL®** - all strengths now approved for inclusion in the Formulary i.e. no need for further consultation on its possible removal. **Equasym XL® and Medikinet XL®** - after considering views from relevant clinicians as to which of these shorter acting preparations should be included in the Formulary, it was decided on 11th March 2010 that the original decision to approve the use of Equasym XL and reject the use of Medikinet XL should stand. Equasym XL approved. Medikinet XL not approved for use.
Qlaira®		√ 26 Nov 09		This was initially refused by the APC at its meeting on 30th July 2009. Not approved. The committee discussed the points raised for the appeal, noting in particular that new trial data was not yet published and that it only compared Qlaira® against placebo. The committee felt that its original decision not to approve the addition of this drug to the Formulary should stand.

Product	Decision + date of decision Approved	Refused	Deferred	Comments / notes
7) Miscellaneous decisions by the APC				
N-Acetylcysteine (Review of status)	√ B 26 Nov 09			To remain in the Formulary for use in the management of interstitial lung disease (in accordance with BTS/SIGN guidance). To be reviewed again when more evidence becomes available.
Alitretinoin	√ R 12 Jan 10			Approved for use in accordance with NICE guidance.
Beclomethasone CFC-free inhalers	26 Nov 09			**Reviewed by a respiratory working group.** Clenil Modulite® is the preferred product, with QVAR® remaining available as an alternative.
Calcium and Vitamin D preparations for use in osteoporosis	26 Nov 09			Calcium and vitamin D products included in the Formulary should be prescribing generically.
Certolizumab pegol (Cimzia)	√ R 11 Mar 10			Approved for use in line with NICE recommendations.
Generic Clopidogrel	√ 29 Sep 09			Generic clopidogrel is approved for use in all the Formulary indications for which clopidogrel is approved. Issues around the stability of various brands in monitored dosage systems would be dealt with by individual organisations via their procurement and contracting processes. Pharmacies and dispensing doctors supplying generic clopidogrel in monitored dosage systems are advised to check that the product they are supplying is sufficiently stable for storing in these devices.
Diazepam 10mg tablets	√ 29 Sep 09			Diazepam 10mg tablets to be removed from the Formulary.
Duloxetine for the Treatment of Neuropathic Pain	√ 04 Jun 09			**Reviewed by an analgesics working group.** Approved for third-line use (after drugs such as the tricyclic antidepressants and gabapentin) in the treatment of neuropathic pain on the advice of pain specialists.
Gabapentin – use for post/ peri-operative analgesia	√ 04 Jun 09			**Reviewed by an analgesics working group.** Approved for use as an adjunct to other treatment in the management of peri/post-operative pain. When used for postoperative pain, it should be supplied by hospitals not GPs.
Insulin pen injection devices (Penmate® and Novopen®)	√ 30 Jul 09			The insulin pen injection devices Penmate® and Novopen® used with insulin cartridges, to be added to the Formulary.
Lidocaine Plasters (Versatis)	√ B 04 Jun 09			**Reviewed by an analgesics working group.** Approved for use on the advice of pain specialists only, and subject to an appropriate trial of efficacy in each individual patient. Lidocaine plasters to be classed as a blue drug.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Modified Release Morphine - Use of cheaper alternatives to MST®		√ 12 Jan 10		**Review requested by an analgesics working group.** A change away from the MST® brand of twice daily modified release morphine will not be made at this point in time.
Nabilone	√ R 04 Jun 09			**Reviewed by an analgesics working group.** Approved for very limited use in the treatment of chronic pain. Its use is limited to use those patients who have not responded to other treatments. Treatment to be initiated by pain consultants and reviewed after about one month. Treatment to be stopped immediately in non-responders. It should remain a 'Red' drug.
Perindopril	√ 12 Jan 10			Perindopril to remain in the Formulary, but lisinopril and ramipril will remain the first-choice ACE inhibitors.
Rivastigmine patches	√ A 12 Jan 10			The original restrictions on the use of rivastigmine patches to remain.
Systane preservative free eye drops	√ 12 Jan 10			Approved for use.
Tramadol -modified release		√ 26 Nov 09		Not approved for inclusion in the Formulary.
Venlafaxine - prolonged release	√ 26 Nov 09			Prolonged release venlafaxine should be prescribing generically.
Warfarin 500 microgram tablets			04 Jun 09	Views to be sought from the various anticoagulant services with a view to obtaining agreement on a North of Tyne policy.
Wound management products	√ 30 Jul 09			The list of wound management products previously considered by the committee was approved and would be added to the Formulary.