The NHS in Newcastle, North Tyneside and Northumberland

North of Tyne Area Prescribing Committee

ANNUAL REPORT April 2010 to March 2011

Executive Summary

The APC continued its work of facilitating clinical decision making across the North of Tyne. 76 products were considered (11 of which were initially considered by the cancer network) and 67% 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 number of shared care guidelines and information leaflets for primary care were developed by the Committee's Shared Care Sub-group.

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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 2011. 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 2010 and March 2011 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
Sue Brent *(Joined the committee Nov 2010)*	Director of Pharmacy	RDTC	2
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
Tim Donaldson	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT	4
Alexander Dyker	Consultant Physician	NUTH	1
Rosie England	Associate Director of Medicines Management	NHS NoT	5
Sue Gordon	Executive Director of Public Health	NHS NoT	2
Matt Grove	Consultant Rheumatologist, NTGH	NHCT	6
Mike Guy	Medical Director	NHS NoT	1
Mike Hannon *(Left the committee Sep 2010)*	Community Pharmacist/North of Tyne PEC	NHS NoT	1
Zahra Irannejad	Head of Prescribing	NNTCH	5
Janet Kelly	Nurse Clinical Manager	NNTCH	3
Matthew Lowery	Trust Antimicrobial Pharmacist Formulary and Audit Pharmacist (from March 2011)	NUTH	5
Tom McCullough *(Joined the committee Nov 2010)*	Community Pharmacist		2
Dominic McDermott (for Bhavana Reddy)	Senior Pharmacist	RDTC	3
Peter McEvedy	GP representative from the PBC community North of Tyne	NHS NoT	5
Andy Reay (for Tim Donaldson)	Prescribing Interface Lead Pharmacist	NTWT	2
Bhavana Reddy *(Left the committee Nov 2010)*	Acting Director of Pharmacy	RDTC	0
Jayanta Sarma	Consultant Microbiologist, NTGH	NHCT	0
Helen Seymour (for Rosie England)	Medicines Management Advisor	NHS NoT	1
Alison Smith	Prescribing Advisor (Provider) – representing prison service	NNTCH	4
Simon Thomas	Consultant Clinical Pharmacologist	NUTH	5
Mritunjay Varma	Consultant Anaesthetist, NGH	NUTH	2
Neil Watson	Clinical Director of Pharmacy and Medicines Management	NUTH	4
Trevor White	GP, Chair of North of Tyne PBC Forum	NHS NoT	1
Steve Williamson	Consultant Pharmacist in Cancer services	NECN	5
Hilary Wynne	Consultant Physician/Chair of NUTH D&T Panel	NUTH	6

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.

- **Medicines Management QIPP Sub-group –** At the March 2011 meeting of the committee it was agreed that the NHS North of Tyne Medicines Management QIPP Board should become a sub-group of the APC. This sub-group will look at the Quality, Improvement, Productivity and Performance (QIPP) work-stream across the North of Tyne area.

Committee Officers

The following is a list of officers to the committee and its main sub groups/committees:

APC – Chair	David Campbell
APC – Vice Chair 1	Simon Thomas
APC – Vice Chair 2	Rosie England
APC – Vice Chair 3	Hilary Wynne
APC – Professional Secretary	David Cook
Formulary sub-committee – Chair	Simon Thomas
Formulary sub-committee – Vice Chair 1	Alexander Dyker
Formulary sub-committee – Vice Chair 2	Zahra Irannejad
Formulary sub-committee – Professional Secretary	Ian Campbell (until March 2011) Matthew Lowery (from March 2011)
Shared Care Group – Chair	Hilary Wynne
Shared Care Group – Vice Chair	Helen Seymour
Shared Care Group – Professional Secretary	Andy Reay

Committee's activities/achievements

During the period from April 2010 to March 2011 the committee carried out the following key activities:

- **Formulary**
    - Work continued on the development and updating of the North of Tyne Formulary.

- **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:
        - 76 products were reviewed

- 51 (67.1%) of these were approved for use
- 25 (32.9%) were rejected for use
- 11 were initially considered by the cancer network and 14 by the North East Treatment Advisory Group
- 6 appeals were made against decisions by the committee. Five decisions were unchanged and one was changed.
- Also 36 miscellaneous decisions were made by the committee.

- **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.
    At the end of March 2011 officially agreed guidelines include:
    - The use of Donepezil, Galantamine and Rivastigmine in the treatment of dementia - May 2007
    - Immunosuppressive treatment following heart and lung transplants - updated Dec 2010
    - Immunosuppressive treatment following liver transplants - Nov 2010
    - Immunosuppressive Treatment Following Renal Transplantation – June 2010
    - Lithium therapy – updated November 2010
    - Methylphenidate for adults - July 2010
    - Methylphenidate for children and young people (updated) - March 2010
    - Naltrexone in Learning Disabilities - July 2009
  - Leaflets were developed to provide information to primary care professionals on drugs classified as BLUE under the 'traffic light' system.
    At the end of March 2011 officially agreed leaflets include:
    - Acetylcysteine - May 2010
    - Agomelatine - Jan-2011
    - Atypical Antipsychotics - Nov 2010
    - Cabergoline - Sept 2010
    - Dekristol-Colecalciferol - Jan 2011
    - Denosumab - Mar 2011
    - Eslicarbazepine - Nov 2010
    - Exenatide - Sept 2010
    - Ibandronic acid - May 2010
    - Lidocaine Plasters - May 2010
    - Melatonin - Sep 2009
    - Midazolam Buccal - Sept 2010
    - Modafinil - Updated Nov 2010
    - Pramipexole - Sept 2010
    - Rasagiline - Sept 2010
    - Ropinorole - Nov 2010
    - Rosuvastatin - May 2010
    - Rotigotine Patches - May 2010
    - Spironolactone and Chlorothiazide Capsules - Sept 2010
    - Triptorelin (Gonapeptyl Depot) - May 2010
    - Venlafaxine (High Dose) - Nov 2010

- **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.

- **Monitored dosage systems/compliance aids**
    - Work continued on developing an assessment process for who should use compliance aids.

- **Links between the APC and the North of Tyne guidelines group**
    - The APC professional secretary was added to the distribution list of the guidelines group and a link was added to the APC website.

- **Formulary compliance**
    - Work was started on assessing compliance with the North of Tyne Formulary across primary and secondary care.

- **Interim Cancer Drugs Fund**
    - In addition to its normal business, the Cancer Network approved a number of drugs for prescribing from the interim cancer drugs fund. As these products were only approved on a temporary basis they were not listed in the APC's Formulary document. However for information, a link to the ICDF list on the Cancer Network website was placed on the APC website.

Committee's Terms of Reference

During the year the committee noted the proposed changes to the NHS and the emergence of local GP commissioning consortia. As a result it was agreed that the terms of reference would need to be reviewed as a priority during 2011-12 to ensure that they reflected the changes in the NHS.

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 of member organisations are requested to acknowledge the details of this report.

APPENDIX 1

Summary of APC Decisions April 10 to March 11

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 2009 - 2010				
Urgosorb®		See notes 13 Jul 10		Application withdrawn by the Tissue Viability Group 13 Jul 2010
2) New Requests				
Abidec® multivitamin drops	√ 08 Mar 11			Approved for use in children and adults. Dalivit® drops to be retained for use in patients requiring a full supplement of vitamin A.
Adrenaline Tartrate (Jext®)	√ 11 Jan 11			Approved.
Branded generic combined oral contraceptives	√ 11 Jan 11			Approved. The six combined oral contraceptives made by Consilient Health should be prescribed for new patients. Prescribers are discouraged from prescribing first line use of brand leaders when the generics are available.
Caphosol®	√ R T 11 May 10 See notes			Approved for use by Dr Charles Kelly only, in those patients having chemo- radiotherapy or radiotherapy to malignancies of the oral cavity, hypopharnyx and oro-pharynx. The use of Caphosol® will be reviewed during the next 6 months with a formal report to the APC being required as a condition of approval.
Cetrorelix acetate 3mg injection (Cetrotide®)	√ R 11 May 10			The 3mg injection is approved for use.
Chlorhexidine impregnated sponge (Biopatch®)	√ 09 Nov 10			Approved
Clostridium Botulinum Toxin A (Azzalure®)		√ 11 Jan 11		**Decision** - The use of botulinum toxin in the treatment of bruxism is not approved as there is insufficient evidence of efficacy as the trials conducted have been too small to assess safety. Dysport® should remain the only product in the Formulary for use in the treatment of hyperhidrosis in Frey's syndrome. Azzalure® is therefore not approved.
Colesevelam (Cholestagel®)	√ 09 Nov 10			Approved. Colesevelam 625mg tablets are approved for use in patients with familial hypercholesterolaemia, with substantial cardiovascular risk and who are unable to tolerate existing treatments, and when colestyramine is not available.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Dronaderone (Multaq®)	√ B 11 May 10			Approved for the limited use that has been requested, until full NICE guidance is published. Initiation of therapy restricted to cardio electrophysiologists. **Restriction removed by the APC on 13 Jul 2010. Treatment should now be initiated by cardiologists.**
Eslicarbazepine (Zebinix®)	√ B 13 Jul 10			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.
Follitropin alfa (Gonal-F®) prefilled pen		√ 09 Nov 10		Not approved. It was felt that the advantage of a prefilled pen formulation was insignificant because this client group is sufficiently motivated to be fully compliant with treatment regimes.
Gaviscon® Advance		√ 08 Mar 11		Not approved. The committee was not convinced that Gaviscon® Advance has any therapeutic advantage over the Formulary choice of alginate, Peptac®.
Golimumab	√ R 08 Mar 11			Approved for use strictly in accordance with the treatment algorithm produced by the rheumatologists and with explicit patient consent on its use. It should not be prescribed for patients who have failed on all of the options currently available.
Hyperbaric Prilocaine 2% (Priloketal®)	√ 08 Mar 11			Approved for use in the indications requested.
Ibuprofen IV (Pedea®)	√ 13 Jul 10			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.
Infloran®	√ 09 Nov 10			Approved.
Juvederm® Ultra 3	√ 13 Jul 10			Approved for use. **Note: the procedure for which Juvederm® ultra is used is NOT available on the NHS.**
Liraglutide (Victoza®)	√ 11 Jan 11			Approved as a second line option, in line with NICE guidance, in patients for whom time and frequency of administration is a problem.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Loperamide (Imodium Instants® Melts)	√ R 07 Sep 10			Approved and given RED drug status.
Micafungin (Mycamine®)	√ 09 Nov 10			Approved
MuGard®	√ 11 May 10			Approved. The use of MuGard® will be reviewed during the next 6 months with a formal report to the APC being required as a condition of approval.
Nicotinic Acid and Laropiprant (Tredaptive®)	√ 13 Jul 10 See Notes			Approved for use in line with NICE GC71 and as a single agent to replace Niaspan®. Niaspan® to be removed from the Formulary.
Phoxilium® 1.2mmol/l phosphate	√ 09 Nov 10			Approved for use in CRRT in patients not requiring reduced potassium or low bicarbonate. Guidelines will be amended accordingly to reflect the risk issues.
Plasma-Lyte 148® and Plasma-Lyte & 5% Glucose®	√ 07 Sep 10			Approved for use in paediatrics in theatres only.
Prucalopride (Resolor®)	√ 11 Jan 11			Approved for use in line with NICE guidance TA211.
Saxagliptin (Onglyza®)		√ 11 Jan 11		Not approved. The potential cost savings were felt not to be great enough to warrant the inclusion in the Formulary of a second gliptin preparation. A new application for saxagliptin could be considered in the future if the product's licence was changed to remove the warning on renal impairment.
Sterile Sodium Chloride 7% (Hypertonic Saline)	√ 11 May 10 See notes			Approved for use in the treatment of patients with CF and bronchiectasis. At this time, it is NOT approved for use in the treatment of COPD unless evidence of its efficacy within that group of patients is provided.
Sucrose 24% solution (Sweet-Ease®) (Unlicensed)	√ 07 Sep 10			Approved.
Telmisartan (Micardis®)		√ 07 Sep 10		Not approved. The committee did not feel that there was sufficient evidence demonstrating the advantages of telmisartan over other angiotensin II receptor antagonists currently included in the North of Tyne formulary.
Testosterone Transdermal Patches (Intrinsa®)		√ 13 Jul 10		Not approved as no sufficient new data has been published.
Tolvaptan (Samsca®)		√ 09 Nov 10		Not approved. Significant advantages, clinically or in terms of cost effectiveness had not been demonstrated.
3) New Formulations & Extensions to Use				
Abatacept (Orencia®)	√ R 09 Nov 10			Approved for the treatment of juvenile idiopathic arthritis in patients aged six years and above (licensed) and under six years (unlicensed). It should only be prescribed with informed consent.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Aripiprazole solution	√ 11 Jan 11			Approved only for doses of 5mg or less, or when titrating patients on doses of increments of less than 5mg, in patients who have difficulty swallowing tablets. Aripiprazole 10 and 15mg orodispersible tablets to be included in the Formulary for doses over 5mg for those patients who have difficulty swallowing tablets.
Ferric Carboxymaltose Ferrinject®	√ 13 Jul 10			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.
Fondaparinux (Atrixtra®)	√ 09 Nov 10			A parenteral anticoagulant requested for use as an alternative to enoxaparin in the treatment of : • Unstable angina (UA) /NSTEMI in patients for whom urgent (<120 mins) invasive management (PCI) is not indicated. • STEMI in patients who are managed with thrombolytics or who initially are to receive no other form of reperfusion therapy. Requested as an alternative to enoxaparin on the grounds that it is recommended in NICE clinical guidance 94 (March 2010); it is considerably cheaper and has a superior safety profile when compared to enoxaparin. **Decision** - Approved.
Forceval® Capsules	√ 11 May 10			Approved for use in patients with severe anorexia nervosa.
Leuporelin (Prostap 3®)		√ 11 Jan 11 See notes		Request for the use of leuporelin as a second line treatment for patients who are unable to tolerate triptorelin was deferred until further evidence could be provided to support the claims that it is associated with fewer side effects, in particular weight gain. No evidence could be found and the application has been withdrawn; however it has been requested that existing patients be allowed to continue their treatment with leuporelin. **Decision** - The request has been withdrawn, but **existing patients** are permitted to continue their treatment with leuporelin.
Lithium for cluster headaches	√ R 08 Mar 11			Approved for use in the treatment of cluster headaches. It is classed as a RED drug for this indication until the Shared Care Working Group has discussed its traffic light classification. The NPSA guideline should be followed including use of a Patient Information Leaflet.
Memantine for the treatment of congenital and acquired nystagmus.	√ 13 Jul 10			Approved for use as a last line drug, after other alternatives have been considered, in the treatment of congenital and acquired nystagmus.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Mesalazine MR tablets (Asacol® MR)		√ 08 Mar 11		Measlazine 800mg MR tablets have been requested for use as a second line treatment for patients with moderate ulcerative colitis that flares, despite 2.4g mesalazine, and it will also be used as an option for patients who have compliance issues due to pill burden. **Decision -** Not approved.
Pramipexole prolonged release (Mirapexin® prolonged release)		√ 07 Sep 10		Requested for use in patients with Parkinson's disease as a monotherapy and as an 'add on therapy', on the grounds that it has potential for improved 24 hour delivery and a decrease in short and long term side effects. Also the once daily presentation offers potential improvements in consistent plasma levels which, in turn, leads to improved symptom control. **Decision** - Not approved as there is no evidence of improved efficacy and only minor reductions in the dizziness of patients.
Salbutamol Easyhaler®	√ 11 May 10			Approved for use in children only, as a second line treatment after the Accuhaler®. There should be a review of the number of patients prescribed the Easyhaler® after six months.
Sonovue®	√ 11 Jan 11			Approved. The current indications of SonoVue are extended to include its use in the diagnosis of pancreatic cancers.
Tacrolimus (Advagraf®)	√ 08 Mar 11			Advagraf® is a prolonged release formulation of tacrolimus that is licensed for once daily administration. Advagraf® has an efficacy and safety profile comparable to the widely used immediate release formulation (Prograf®). It has been requested for use for prophylaxis of organ rejection in kidney and liver transplantation. A branded generic, Adoport®, which is considered bioequivalent to Prograf®, has recently become available as well. There are potential for savings to be made both in Primary Care and Secondary Care from replacing Prograf® with either Advagraf® or Adoport®. **Decision -** Advagraf® approved for use in patients who are currently prescribed Prograf®. *De novo* patients should be prescribed Adoport®.
4) Products Considered by NECDAG				
Bendamustine (Levact®)	√ R 08 Mar 11			Approved for first line treatment of chronic lymphocytic leukaemia (Binet stage B or C) in patients for whom Fludarabine combination chemotherapy is not appropriate.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Fulvestrant (Faslodex®)	√ R 07 Sep 10			Approved for use in the following situations: Patients who are post-menopausal and oestrogen receptor positive advanced or metastatic breast cancer with any of the following: 1. Have relapsed on aromatase inhibitor (AI) therapy in advanced disease 2. Patients with severe joint pains exacerbated by AI therapy 3. Patients with tablet compliance issues (swallowing problems) 4. Patients in whom certainty of administration is an advantage AND – there is agreement from the Local Breast MDT that initiation of fulvestrant is the best treatment option available to the patient.
Gefitinib (Iressa®)	√ R 09 Nov 10			Approved by NICE (TA192 – July 2010) as an option for the first-line treatment of people with locally advanced or metastatic NSCLC.
Lapatinib (Tyverb®)		√ 09 Nov 10		Proposal for the use of Lapatinib in combination with an aromatase inhibitor (AI) for the treatment of metastatic breast cancer, not currently intended for chemotherapy. **Decision** - Rejected as the cost effectiveness case was not met.
Nab-paclitaxel (Abraxane®)	√ R 07 Sep 10			Accepted for restricted use within its current license for metastatic breast cancer patients who cannot tolerate standard taxanes.
Pemetrexed (Alimta®)	√ R 07 Sep 10			Approved by NICE (TA190 – June 2010) for: • Maintenance treatment for locally advanced or metastatic non-small-cell lung cancer NSCLC (non-squamous cell histology) if disease has not progressed immediately following platinum-based chemotherapy in combination with gemtitabine, paclitaxel or docetaxel • People who have received pemetrexed in combination with platinum as first-line chemotherapy cannot receive pemetrexed maintenance treatment.
Rituximab (Mabthera®)	√ R 07 Sep 10			Given restricted approval for the treatment of nodular lymphocyte-predominant Hodgkin lymphoma (NLPHL).
Rituximab (Mabthera®)	√ R 09 Nov 10			Approved for treatment of newly diagnosed mantle cell NHL in fit patients aged <60 years old.
Rituximab (Mabthera®)	√ R 09 Nov 10			Approved by NICE (TA193 – July 2010) in combination with fludarabine as a treatment option for people with relapsed or refractory CLL (with certain exceptions).
Rituximab (MabThera®)	√ R 08 Mar 11			Aproved for first line maintenance in follicular non-Hodgkin's lymphoma.

Product	Decision + date of decision Approved	Refused	Deferred	Comments / notes
Trastuzumab (Herceptin®) with cisplatin and fluorouracil/ capecitabine	√ R 13 Jul 10			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				
Agomelatine (Valdoxan®)	√ A 07 Sep 10			An appeal was made of the NETAG recommendation (October 2009) regarding the use of agomelatine within its licensed indication for the treatment of major depressive episodes in adults. **Decision** - Recommended 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 specialist mental health physicians. After a minimum of 12 week's treatment, responsibility for prescribing may be transferred to primary care subject to local shared care and commissioning arrangements.
Amifampridine phosphate (Firdapse®)		√ 07 Sep 10		An appraisal of amifampridine phosphate was conducted for the treatment of Lambert-Eaton myasthenic syndrome (LEMS). **Decision** – Not recommended for use within NHS North East. The group did not consider amifampridine phosphate to be cost-effective treatment contingent on the continued availability of unlicensed amifampridine (3,4-diaminopyridine).
Anti-vascular endothelial growth factor (aVEGF) therapies	√ 09 Nov 10			aVEGF therapies, specifically bevacizumab and ranibizumab, were considered as adjuncts to laser therapy in the treatment of diabetic macular oedema. **Decision** - Recommended for use in NHS North East for the treatment of centre-involving diabetic macular oedema as an adjunct to standard laser therapy.
Anti-vascular endothelial growth factor (aVEGF) therapies	√ 08 Mar 11 See notes			aVEGF therapies, bevacizumab and ranibizumab, were considered in the management of macular oedema secondary to retinal vein occlusion. **Decision** - Bevacizumab 1.25mg using a 'when required' (PRN) regimen is recommended for use in NHS North East in the management of macular oedema secondary to retinal vein occlusion. This is considered a more a cost effective treatment option in RVO compared with ranibizumab.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Bosentan (Tracleer®)		√ 11 May 10		An appraisal was conducted for the use of bosentan in the management of digital ulcers in patients with systemic sclerosis. **Decision** – Not approved for use within NHS North East.
Dabigatran	√ 08 Mar 11 See notes			NETAG considered the cost impact of the use of dabigatran for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation based on preliminary recommendations from the Cardiac Rhythm Management Group of the North east Cardiovascular Network. **Decision** – Warfarin recommended as remaining the treatment of choice for patients with non-valvular atrial fibrillation and a CHADS-2 score ≥ 2, except for: 1. Patients with specific contra-indications to warfarin, for example those with a bleeding risk defined by a valid bleeding score, important and unavoidable drug interactions, scheduled interventions such as cardioversion, or other accepted criteria. 2. Patients who have failed to demonstrate adequate anticoagulant control based on a threshold of time-in-therapeutic range (TTR) ≥ 50% after a defined period of warfarin therapy. In these circumstances dabigatran is considered a cost-effective treatment option.
Deferasirox (Exjade®)	√ 11 May 10 See notes			An appraisal of deferasirox was conducted for the treatment of chronic iron overload in patients with haemolytic anaemias such as beta-thalassaemia and sickle cell anaemia. **Decision** – Only recommended for use when treatment with desferrioxamine is no longer considered to be appropriate due to progressive iron overload despite maximally tolerated doses of desferrioxamine. Continued treatment with desferrioxamine might not be considered appropriate in cases of confirmed intolerance, hypersensitivity, or persistent non-compliance with therapy.
Gastroelectrical stimulation for gastroparesis		√ 11 May 10		An appraisal was conducted of gastroelectrical stimulation using the Enterra® device for the management of gastroparesis. **Decision** – Not approved
Intravitreal dexamethasone implant (Ozurdex®)	√ 09 Nov 10 See notes	√ 09 Nov 10 See notes		Considered within its licensed indication for the treatment of macular oedema secondary to branch or central retinal vein occlusion. **Decision** – Only recommended for use in NHS North East for the treatment of macular oedema in cases of non-ischaemic central retinal vein occlusion. Not recommended in any cases of ischaemic or branch retinal vein occlusion.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Left atrial appendage occlusion with the Watchman® device		√ 07 Sep 10		An appraisal was conducted of the use of the Watchman® left atrial appendage occlusion device for stroke prevention in patients with paroxysmal non-valvular atrial fibrillation. **Decision** – Not recommended for use within NHS North East.
Leukapheresis with Adacolumn®		√ 08 Mar 11		NETAG considered the Adacolumn® leukapheresis treatment system withinits approved indication for the treatment of moderate to severe active inflammatory bowel disease. **Decision** – Not recommended for use within NHS North East for the treatment of inflammatory bowel disease.
Roflumilast (Daxas®)		√ 07 Sep 10		An appraisal was conducted of the use of roflumilast in its licensed indication for the maintenance treatment of severe COPD associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment. **Decision** – Not recommended for use in the management of severe COPD within NHS North East.
Sativex®		√ 09 Nov 10		NETAG considered the use of Sativex®, a cannabinoid oromucosal spray, for use within its licensed indication for the treatment of moderate to severe spasticity due to multiple sclerosis. **Decision** – Not recommended for use within NHS North East for the treatment of spasticity due to multiple sclerosis.
Tocilizumab (RoActemra®)	√ 07 Sep 10 See notes	√ 07 Sep 10 See notes		An appraisal was conducted of the use of tocilizumab for juvenile idiopathic arthritis (JIA). **Decision** – Recommended as an alternative treatment to anakinra for patients with systemic onset JIA who have already received treatment with etanercept and adalimumab. Not recommended for polyarticular JIA.
6) Appeals against earlier decisions by the APC				
Botulinum toxin type A (Botox®)		√ 11 Jan 11		Requested for the prophylaxis of headaches in adults with chronic migraine. An application was considered and refused by the APC at its meeting on 9th November 2010. **Decision** – Not approved.
Capsaicin 8% patch (Qutenza®)		√ 11 Jan 11		A topical analgesic requested for use in the treatment of neuropathic pain in HIV patients and other non-diabetic patients. An application was considered and refused by the APC at its meeting on 9th November 2010. **Decision** – Not approved.

Product	Decision + date of decision Approved	Refused	Deferred	Comments / notes
Dutasteride (Avodart®)		√ 09 Nov 10		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. A new application was considered and again refused by the APC at its meeting on 13th July 2010. **Decision-** Not approved.
Fesoterodine (Toviaz®)	√ R 09 Nov 10			This was initially rejected by the APC on 25th November 2008 and again on 11th May 2010 after new clinical evidence had been considered. An appeal was considered by the APC on 7th September 2010 where new evidence was presented to support its use. This was referred to the Formulary Subcommittee for more detailed consideration. As a result it was felt that there may be some clinical and financial benefit to be gained from fesoterodine as it is claimed that it can reduce the need for surgery. **Decision** – Approved for use in the treatment of overactive bladder syndrome. It should be prescribed by specialists only for patients that would otherwise require surgery. Patients should be subject to a trial of therapy and the drug discontinued if ineffective.
Omalizumab in children aged 6-11 years old		√ 08 Mar 11 See notes		Recent NICE guidance states that omalizumab is **not** recommended for the treatment of severe persistent allergic asthma in children aged 6 to 11 years. Omalizumab for use in children aged 6-11 years was removed from the Formulary by the APC at its meeting on 11th January 2011. However children currently receiving omalizumab for the treatment of severe persistent allergic asthma were allowed the option of continuing treatment until it was considered appropriate to stop. **Decision** – Appeal rejected.
Telmisartan (Micardis®)		√ 09 Nov 10		Requested for use in the treatment of hypertension and cardiovascular protection. An application was considered and refused by the APC at its meeting on 7th September 2010. **Decision** - Not approved. The committee discussed the points raised for the appeal and reviewed the original application and evaluation documentation but felt that its earlier decision not to approve the use of this drug should stand. The committee also noted that there were already **four** angiotensin-II receptor antagonists on the Formulary and that telmisartan should not be used on a non-formulary basis.
7) Miscellaneous decisions by the APC				

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Abatacept	√ R 08 Mar 11			Recently considered as a treatment option in NICE TA 195 (Rheumatoid arthritis - drugs for treatment after failure of a TNF inhibitor). **Decision** - Approved for addition to the Formulary for use according to NICE guidelines.
Agomelatine	√ B 09 Nov 10			There had been some confusion as to the traffic light status of Agomelatine following the recent NETAG recommendation. The shared care group had suggested that specialists could refer patients back to their GPs at 24 weeks, if clinically indicated, as this would allow all required monitoring to be carried out in secondary care. **Decision** – Agomelatine is classified as a BLUE drug with the first 24 weeks of treatment being provided by (and hence monitoring) secondary care.
Dronaderone	√ R 08 Mar 11			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. **Decision** - Owing to this alert, the traffic light status of dronaderone is changed from BLUE to RED although the Shared Care Group may suggest an alternative.
Eye caps®/Ocuvite®		√ 11 May 10		Refused. There is insufficient evidence to endorse the use of these products.
Cabergoline and pergolide	√ 11 May 10 See notes			Pergolide to be removed from the Formulary and there should be a review of patients currently prescribed pergolide. Cabergoline to remain in the Formulary for initiation by endocrinologists. Clarification as to the specific indications for which cabergoline is being used is being sought from endocrinologists and neurologists. Parkinsonism to be removed as an indication.
Clobetasol propionate with neomycin and nystatin (Dermovate NN®)	√ 07 Sep 10			Previously included in the Formulary, but was discontinued by the manufacturer in 2008. It is now available from a different manufacturer. **Decision** - Approved.
Dekristol®	√ G 09 Nov 10			There are regular queries from primary care about the prescribing and availability of Dekristol® and this has led to discussion about the traffic light status of Dekristol®. **Decision** - Dekristol® remains a GREEN drug and information on prescribing and availability will be developed for the APC website.
Denosumab (Prolia®)	√ B 09 Nov 10			Approved for use by the APC on 7th September 2010. Subsequent request that the traffic light status be clarified. **Decision** - Approved for use in accordance with NICE and classified as a BLUE drug. An information leaflet will be prepared.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Diltiazem – formulary brand	√ 07 Sep 10 See notes			Zemtard® to be the Formulary brand of choice for starting new patients on long acting diltiazem. This would be reviewed in 18 months.
Dyes, Patent Blue and Methylthioninium Chloride	√ 13 Jul 10 See Notes			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.
Escitalopram		√ 08 Mar 11 See notes		The Medicines Management Committee of NTW Trust had considered an application for escitalopram; the Committee had not been persuaded by the evidence so a request had not been submitted for consideration by the Formulary Subcommittee. The Committee agreed that there was a limited place in therapy for escitalopram and agreed that it should continue as a fourth line treatment, using the non formulary procedure.
Etonogestrel (Nexplanon®)	√ 09 Nov 10			Etonogestrel (Implanon®) has been replaced by Etonogestrel (Nexplanon®) which differs from Implanon® in that it is impregnated with radio opaque material. **Decision** – Approved. Etonogestrel (Nexplanon®) to replace Etonogestrel (Implanon®) in the Formulary.
Growth Hormone Review	√ 08 Mar 11 See notes			The Formulary Subcommittee considered a review of growth hormones with a view to rationalising this section of the Formulary. **Decision** – 1. Given that there is no evidence of difference in efficacy and safety between the available preparations Omnitrope® should be used in all de novo paediatric patients. Using Omnitrope® in all de novo patients would realise a maximum recurring saving of £18,500 pa. The uptake of Omnitrope® will be monitored and it is anticipated that it will make up the majority of new prescribing within 12 months. 2. The healthcare professional involved may consider another device is necessary, for example in true needle phobia. Specific criteria should be drawn up to justify the use of the more expensive preparations. 3. Genotropin® MiniQuick will be maintained to ensure availability for patients when travelling. 4. The use of other assay services should be explored to facilitate the use of lower cost rhGH preparations in adult patients. 5. There is an expectation that existing patients, where appropriate, will be switched to the low cost rhGH preparations. This would realise maximum savings of approximately £200,000 pa.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Healthy Start Vitamins	√ 09 Nov 10			Requested for the prevention of Vitamin D deficiency in children and pregnant women. These formulations are prepared for the NHS and recommended in NICE guidance. Department of Health policy offers the Healthy Start Vitamins to pregnant women and children less than 4 years. They would only be available through clinics and from midwives and not using FP10 prescriptions. **Decision** - Approved.
Hormone replacement therapy	√ 13 Jul 10 **Evorel® Sequi** **Premique® Low Dose** **Climaval®**	√ 13 Jul 10 **Utrogestan®** **(See notes)**		• **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
Human Chorionic Gonadotrophin (hCG)	√ 08 Mar 11 See notes			This is classified as a RED drug for use in fertility treatment. However it has been used for many years in the treatment of hypogonadism which is more appropriate as BLUE. **Decision** – Approved. hCG to be classified as a BLUE drug when used for hypogonadism.
Infacol®	√ 07 Sep 10			Approved. To be added to the North of Tyne Formulary for use in endoscopy procedures.
Insulin KwikPens®	√ 11 Jan 11			Lilly are discontinuing the Humalog® pens and the alternative is the KwikPen®. **Decision** – Approved. Insulin KwikPen® to be added to the Formulary.
Mercaptamine	√ 09 Nov 10 See notes			Mercaptamine to be added to the Formulary document.
Mesalazine products	√ 13 Jul 10 **Mesren® MR** **Asacol® MR** **Pentasa® sachets** (see notes)	√ 13 Jul 10 **Mesavant® XL** (see notes) **Asacol® 800** **Olsalazine**		• 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.
Mesalazine 1g Suppositories (Pentasa®)	√ 07 Sep 10			Approved. To be added to the North of Tyne Formulary.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Modafanil - MHRA drug safety advice	√ 07 Sep 10 See notes			The European Medicines Agency has recommended that the use of modafinil should be restricted to treat only sleepiness associated with narcolepsy, and that it should no longer be used for the treatment of excessive sleepiness associated with obstructive sleep apnoea or chronic shift work sleep disorder. **Decision** - The Formulary will be amended accordingly.
Modafanil - use for idiopathic hypersomnia		√ 09 Nov 10		Request to have Modafinil listed in the Formulary, as previously, for idiopathic hypersomnia, contrary to recent advice from the EMEA. **Decision** – Refused. Modafinil not to be listed in the Formulary for idiopathic hypersomnia.
Neomycin/ Colistin/ Nystatin - Selective decontamination of digestive tract	√ R 09 Nov 10			Request that the traffic light status of neomycin be changed from PURPLE (Tertiary Care only) to RED. This would allow neomycin to be prescribed in secondary care settings for the decontamination of the digestive tract. **Decision –** Approved.
Nifedipine/ Diltiazem	√ 13 Jul 10 See notes			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.
Paracetamol IV - MHRA drug safety advice	√ 07 Sep 10 See notes			In paediatric areas only, the 50ml formulation should be stocked.
Perindopril in stroke prevention	√ 07 Sep 10 See notes			The APC confirmed that perindopril is third line for all indications including prevention of stroke, and that the Formulary should be updated to clarify this.
Pioglitazone / Metformin (Competact®)		√ 09 Nov 10 See notes		In the light of the recent safety alert and withdrawal of Rosiglitazone, consideration was given as to whether Competact® could be used as an alternative to Avandamet® (a combination of rosiglitazone and metformin). **Decision** – A formal application will be required before Competact® could be considered for inclusion in the Formulary.
Prednisolone enteric coated – removal from formulary	√ 07 Sep 10			Enteric coated prednisolone would be removed from the Formulary though each organisation would manage the process locally.

Product	Decision + date of decision			Comments / notes
	Approved	Refused	Deferred	
Pregabalin and amitriptyline in neuropathic pain management	√ 11 May 10 See notes			The NICE guidance was considered and it was felt that it was still appropriate to use gabapentin (the use of lower strength capsules being more cost effective). Therefore the Formulary would be amended to state: **For neuropathic pain** – First choice – amitriptyline Second choice – gabapentin Third choice – pregabalin Alternatives – as currently listed including the use of tramadol in line with the NICE guideline **For painful diabetic neuropathy** – First choice – duloxetine Second choice – amitriptyline Third choice – gabapentin Fourth choice – pregabalin Alternatives – as currently listed including the use of tramadol in line with the NICE guideline.
Rosiglitazone - MHRA drug safety advice	√ 07 Sep 10 See notes			The MHRA has issued a reminder about current advice for the use of rosiglitazone in the treatment of diabetes. **Decision** - Rosiglitazone to remain on the Formulary for existing patients and where the risks, as related in the MHRA notes, have been discussed with them.
Sitaxentan		08 Mar 11 See notes		Sitaxentan has been discontinued by the manufacturers and this will be removed from the North of Tyne Formulary.
Ustekinumab	√ R 11 May 10			Approved for use in line with NICE recommendations.
Venlafaxine (Switching of Venlafaxine MR capsules/tablets to immediate release tablets)	08 Mar 11 See notes			A proposal was considered for a programme to switch appropriate patients taking venlafaxine modified release (MR) to the same total daily dose of immediate release (IR) venlafaxine tablets. This change would be implemented only for those patients taking doses of up to 225mg daily of modified release venlafaxine. **Decision** – Approved.
Vitamin D guidelines		√ 07 Sep 10 See notes		The guideline stated that intramuscular ergocalciferol injection may be administered orally. There is no evidence to support this. **Decision** - The oral use of intramuscular ergocalciferol injection will not be added to the Formulary.
Vitamin K 1mg capsules	√ 07 Sep 10			The 1mg vitamin K capsule to be included in the North of Tyne Formulary alongside the existing preparations.