North of Tyne
Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 12th March 2013 at Northumbria House, Cobalt Business Park, North Tyneside

Present

Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Ian Campbell (IC)	Assistant Director of Pharmacy	NUTH
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Sue Dickinson	Director of Pharmacy	RDTC
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Alexander Dyker	Consultant Physician	NUTH
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Peter McEvedy (PMcE)	GP and Prescribing Lead	NHS Northumberland CCG
Tamsin Oswald (TO)	Consultant Microbiologist	NHCT
Helen Seymour	Senior Medicines Management Advisor	NHS NoT
Susan Turner (STu) (Professional Secretary)	Medicines Management Advisor	NHS NoT
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NECN
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Sue Gordon (SG)	Executive Director Public Health	NHS NoT
Janet Kelly	Chief Matron for Community Services	NHCT
John Ross (JR)	Patient Representative	John Ross (JR)
Wendy Ross	GP and Prescribing Lead	NHS Newcastle North and East CCG
Simon Thomas	Consultant Clinical Pharmacologist	NUTH

NoT LPC	North of Tyne Local Pharmaceutical Committee
NECN	North of England Cancer Network
NHCT	Northumbria Healthcare NHS Foundation Trust
NHS NoT	NHS North of Tyne
NTWT	Northumberland Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre

2013/21 Declarations of interest
No relevant declarations made.

2013/22 Appeals

Cefixime – prevention of irinotecan induced diarrhoea in children
The application to use cefixime to prevent diarrhoea in children undergoing treatment with irinotecan had been refused at the January meeting.

Dr Quentin Campbell Hewson presented some additional information for the committee to consider.
It was noted that:

- Irinotecan is used second line in a small number of children annually for a range of about 10 individually rare conditions. This means that the time taken to establish a statistically robust evidence base for associated treatments is lengthy and not yet well established.
- Children are treated with high intensity irinotecan in order to achieve cure, the rates of which are approx 80%.
- The diarrhoea associated with irinotecan is severe and associated with a mortality rate of 5%. This limits the dose of irinotecan that can be given and therefore compromises effective treatment.
- Irinotecan is inactivated by glucuronidation in liver. The inactive metabolite is excreted into the gut where it is de-glucuronidated by gut bacteria back to the active metabolite. It is this active metabolite that causes the intestinal toxicity.
- Cefixime is given along with the irinotecan and for 4-5 days after cessation of therapy to eradicate the gut bacteria responsible for conversion back to the active metabolite.
- Although there is an ongoing clinical trial for use in some patients the numbers who meet the trial criteria are small and there is a wish to extend use to patients outwith the trial criteria.

Concern was expressed at the potential of cefixime to increase rates of C. Diff, particularly as it is a drug which has some systemic absorption. It was noted that this is a cephalosporin antibiotic which are associated with increased risk. The applicant acknowledged the potential risk, although highlighted to the committee the fact that this needs to be weighed against both the associated mortality from ineffective treatment doses and the mortality rates associated with the original irinotecan induced diarrhoea. It was also noted that large quantities of broad spectrum antibiotics are already necessarily used in oncology.

On reflection the committee acknowledged that although the group has no jurisdiction over clinical trials, the request is for use outwith the ongoing trial and the lack of robust evidence is due to the low numbers of patients and the rarity of the conditions being treated. Approval would help to inform the evidence base. The concern over potential increase in C Diff cases was noted but it was felt that the associated mortality from ineffective treatment doses and the mortality rates

associated with the original irinotecan induced diarrhoea needed to be weighed against this potential risk.

Decision: Cefixime
Approved for the prevention of irinotecan induced diarrhoea in children

Flutiform
Flutiform had been requested for the maintenance treatment of asthma. This application was refused in January as, whilst it was appreciated that there was a potential for some cost savings at higher doses, it was anticipated that this cost advantage was not large and could be diminished when Seretide comes off patent. It was also noted that a significant amount of work had gone into switching patients from the Seretide Evohaler to the Accuhaler, and that Flutiform is more expensive than the Accuhaler.

Dr Chris Stenton and Dr Mike Scott presented some additional information for the committee to consider.
It was noted that:

- The original cost saving calculations had been based on secondary care estimates of use and in fact most of the prescribing of this product would be undertaken in primary care. The potential savings had therefore been underestimated and had now been recalculated and presented to the committee.
- Whilst Seretide was now off patent, there had been little reduction in costs and indeed an assumption that inhaler devices reduced in price to the same extent as standard oral preparations of medicines following patent expiry did not appear to be borne out in practice.
- Any cost savings achieved from use of this product would be reinvested in improvements to patient care.

On reflection the committee acknowledged the increased cost saving calculations and therefore upheld the appeal.

Decision: Flutiform
Approved for the maintenance treatment of asthma.

2013/23 Minutes and decision summary from the meeting held on Tuesday 8th January 2013.
These were accepted as a true record.

2013/24 Matters arising not on the agenda.
None.

2013/25 Report from the Formulary Sub-committee

Minutes and recommendations from the meeting held on Thursday 28th February 2013.
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**.

The following specific points were highlighted for further consideration:

The applications for Tadalafil (for post radical prostatectomy), Gonal F and Palifermin had all previously been deferred pending additional information from the applicants. These applicants have now been approached regarding submission timescales for this outstanding information and have agreed that the applications can be considered as withdrawn at this point.

Eculizumab

Eculizumab has been requested for the prevention of acute cardiac rejection post-transplant.
It was noted that while some evidence of efficacy in the reduction of antibody mediated rejection (AMR) has been demonstrated in kidney transplantation, the evidence of clinical effectiveness specifically in paediatric cardiac transplantation is limited.
The Formulary Subcommittee felt that the evidence of efficacy in kidney transplantation might suggest proof of concept that it would be efficacious in AMR in paediatric cardiac transplantation and felt that while there are some risks, those risks are not prohibitively high. The FSC felt that clinical approval could potentially be recommended, although it was recognised that the current commissioning arrangements for such a specialised drug are unclear in the transition period.
It was agreed that this was something that should fall under the remit of the Local Area Team of the NHS Commissioning Board and until a national decision was made to the appropriateness of use, all requests should be sent to that organisation as an IFR, in line with the recommended processes for such approvals post 1/4/13.
Concern was expressed that this decision would result in delays in decision making and cause concern for NUTH clinicians. ML agreed to discuss the new processes further with the applicant.

Decision: Applications for the use of eculizumab for the prevention of acute cardiac rejection post-transplant should be referred to the Local Area Team of The NHS Commissioning Board. In the absence of a national decision relating to this use these applications will be as IFRs.

Forceval Soluble

Forceval Soluble is a multi vitamin and mineral supplement which has been requested for short term use in patients who are unable to swallow Forceval capsules.
This product is significantly more expensive than the Forceval capsules and therefore the decision was deferred by the Formulary Subcommittee until clarification was sought as to whether Forceval Soluble has nutritional advantages over alternatives such as Dalivit and Abidec.
Additional information now clarifies that Forceval Soluble contains trace elements that are not present in the other formulary products.

Decision: Forceval Soluble
Accepted for short term use in patients who are unable to swallow Forceval capsules.

Plenadren MR

Plenadren is a modified release hydrocortisone preparation that has been designed to more closely mimic the natural circadian rhythm than the immediate release preparation. It has been requested for the treatment of adrenal insufficiency in patients with co-existing diabetes, with brittle control or poor compliance. At the FSC meeting it was noted that whilst there is evidence of some improvements in glycaemic control the clinical significance of changes were unclear and that the number of diabetic patients in the study was low.
Additional information has since been circulated to members which highlighted that whilst the change in HbA1c in the non-diabetic group is not clinically impressive (0.1% reduction, p=0.0006), over the 12 weeks of the licensing study, (Johannsson et al. J Clin Endocrinol Metab 2012, 97:473) the patients with coexisting Addison's disease and type 1 diabetes had a 0.6% improvement in HbA1c (p=0.0039) which the applicant feels is impressive over a short period of time and is the equivalent change of adding an additional anti diabetic agent for someone with type 2 diabetes.
The committee considered this additional information and still feel that the main advantage being argued for is the reduction in number of tablets/daily doses of steroid. As these patients will still need to have multiple daily doses of other medications, it was not felt that this potential benefit justified the increased cost of this product. The initial formulary subcommittee recommendation was therefore endorsed.

Decision: Plenadren
Refused.

Clopidogrel Suspension

This has been requested for use in paediatric patients who are unable to swallow tablets. It was noted that the suspension is 100 times more expensive than the tablet formulation; however the difficulties in ensuring the correct dose is given if the tablets are crushed were acknowledged. ADP inhibition is routinely measured in children on Berlin Heart Devices and it has now been clarified that using the liquid preparation in these children allows an accurate dose to be more easily given and therefore gives a greater chance of achieving adequate ADP inhibition on clopidogrel. If this is not achieved, patients need to be switched to Prasugrel.

Decision: Clopidogrel Suspension
Approved for children with Berlin Heart Devices.

Alendronic Acid solution

Alendronate solution has been requested on the grounds that it is cheaper than strontium ranelate, which has been used as an alternative in some patients who have swallowing difficulties.
The Subcommittee had noted that while alendronic acid solution is cheaper than strontium ranelate, it would be preferable to treat such patients parenterally instead. The APC sought clarity on this assumption as the total cost of the parenteral product is currently higher than the alendronate solution.
ML clarified for the committee that concerns had also been raised as to the safety of a bisphosphonate solution in patients with swallowing difficulties and this had contributed to the decision.

Decision: Alendronic acid solution Refused

The committee endorsed the remainder of the recommendations made by the subcommittee and these will be incorporated in the next formulary update.

2013/26 Report from the Shared Care Group (SCG).

HW highlighted the following points from the minutes:

- The NHS Commissioning Board will now have responsibility for deciding on the commissioning and funding arrangements of some drugs. It had therefore been suggested that the Local Area Team of this Board should be represented at the APC and/or SCG. DC has approached the lead pharmacist and he has agreed to attend if invited where decisions relate to products which fall under the remit of the Board. As the group will continue to have a role in agreeing shared care arrangements across North of Tyne for drugs not commissioned at a national level, the members agreed that it would be beneficial to have a medical representative and a representative from commissioning from NTW on the Shared Care Group. TD has agreed to progress this.
- Agomelatine Information for primary care – this had been updated in line with new monitoring recommendations. This was approved and will be made available on the North of Tyne APC website.
- Denosumab Information for primary care – this has been updated to include the off license use in men agreed by the APC. The updated leaflet was endorsed for inclusion on the website.
- Cinacalcet in primary hyperparathyroidism - The APC, at its meeting of the 13th November 2012, agreed that cinacalcet for use in primary hyperparathyroidism for patients where surgery is not appropriate or contraindicated would be approved as amber, subject to the production of a shared care guideline. This guideline was now submitted for approval. It was noted that this is a tariff excluded drug that falls under the remit of the NHS Commissioning Board moving forward and therefore a local decision such as this will be funded by CCGs. It was agreed that the shared care guideline would be adopted for existing patients only but that any new requests for this indication would need to go the NHS Commissioning Board as an IFR request. The committee expressed concern over the complexity of the new arrangements relating to tariff excluded drugs and DC agree to write to the NHS CB to outline these concerns.
- Melatonin for childhood insomnia - the shared care guideline for melatonin for the management of sleep-wake disorders in children of 18 years and under, produced in response to GPs' concerns about its long term use off licence in children, often in combination with other psychotropic drugs, was approved by the group. The group agreed that further work was needed to rationalise the available preparations approved for use.
- Erythropoietin Shared Care Guideline - there are ongoing commissioning issues relating to this guideline but the clinical information within the guideline was approved. Members agreed there should be a new section of the website for "Guidelines approved but not yet commissioned".
- Atomoxetine in children and young people - there are some ongoing commissioning issues relating to this guideline but resolution is expected

shortly. The clinical information within the guideline was approved and the guideline will be implemented once these are resolved.

- Memantine Information for primary care – Agreement has now been reached regarding ongoing monitoring of patients with dementia in primary care and therefore this information leaflet was approved.
- Acetyl cholinesterase inhibitors Information for primary care – approved.

Dr Wynn raised concerns regarding an apparent refusal from primary care to continue prescribing azathioprine for a patient where monitoring arrangements had not been clearly agreed and was concerned that this was not an isolated situation. The committee echoed these concerns and HS agreed to look into the background to this further as full details were not available to the committee.

2013/27 Report from the Anti-microbial Chemotherapy subcommittee.
No report is due.

2013/28 Quality, Improvement, Productivity and Performance (QIPP)
Draft minutes from the meeting on 16 January 2013 were received.

2013/29 NE(NHS)TAG Proposal
The APC considered a document circulated on the potential future of NETAG. With the changing NHS environment drug decision making groups across the region, like the NoT APC, will need clarity on this ASAP. Without this there is a risk either of duplication of work or the referral of certain decisions back into alternative groups which may introduce delay in decision making and/or risk postcode prescribing again. The role of the Commissioning Board in the new landscape was recognised but there are still several grey areas where clarification of decision making processes would be welcomed.
DC agreed to contact Mike Prentice, medical director of the Local Area Team of the NHS Commissioning Board, to seek clarity with regards to Local Decision making processes and the future of "new" NETAG.

2013/30 Blood Glucose testing guidelines/devices
The guideline submitted to the committee was approved subject to a minor change to the document to reflect the fact that it is intended for use by all clinicians across the North of Tyne area working with patients with diabetes.
ST will liaise with the authors to ensure this change is done before onward dissemination.

2013/31 Buccal Midazolam
The APC previously had previously asked for a task and finish group to look at the issues around changing from the current unlicensed preparation that is used across the area to the licensed product. ML explained that this group had met and that there are still a number of issues that would need resolved before a change in practice could be recommended. The current licensed product, Buccolam is only licensed in children and many adults have need of buccal midazolam as well. Epistatus, which is still unlicensed, is preferred in some instances due to the smaller volume of liquid required to deliver the appropriate dose.
DC asked for a resolution to the outstanding issues to be brought back to the committee in due course.

2013/32 Documents previously circulated by e-mail

- NECDAG CDF decision summary for Abiraterone for metatstic castration resistant prostate cancer (chemotherapy naive)
- NETAG Decision summary notice - Anti-thymocyte globulin for first-line treatment of adult aplastic anaemia

- NETAG Decision summary notice - Ulipristal (ellaOne®) for post-coital contraception: Updated appraisal
- NETAG Decision summary notice - Aflibercept (Eylea®) for neovascular age-related macular degeneration

The above recommendations were noted and endorsed by the committee.
SW informed the committee that his role as the NECDAG representative on the committee would cease on 31st March. He will however continue to have a role in the North East as a representative of the Cancer Network and will be working closely with the NHS Commissioning Board in cancer medicine decision making. The committee have valued his contribution in the past and requested that his membership continues as a representative of the Cancer Network/ Commissioning Board for Chemotherapy medicines.
This was confirmed.

2013/33 APC Guidelines and Statements for review

None

2013/34 NICE

The following NICE TAGs were noted. The recommendations within them were endorsed by the committee and the North of Tyne Formulary will be updated to reflect these decisions.
NICE Technology Appraisals published in January and February

- TA271: Diabetic macular oedema - fluocinolone acetonide intravitreal implant
- TA272 : Urothelial tract carcinoma (transitional cell, advanced, metastatic) – vinflunine
- TA273 : Hyperplasia (benign prostatic) - tadalafil (terminated appraisal)
- TA 274: Macular oedema(diabetic) – ranibizumab
- TA275: Stroke and systemic embolism (prevention, non-valvular atrial fibrillation) – apixaban

All approved products will be added to the North of Tyne formulary in line with the NICE TAGs. The committee agreed that ML would ask Dr Skinner to convene a group which would develop some guidelines on the relative positioning of apixaban in relation to the other agents available in the prevention of non-valvular AF.

2013/35 Chair's action

None

2013/36 Any other business

1. In January (2013/10) the committee considered a letter from Sir David Nicholson, sent to all NHS organisations, reminding them of the requirement that drugs approved by a NICE TA guideline should be included in local medicines formularies and these formularies should be published online and be patient and stakeholder accessible.
   Keith Ridge, the DH Chief Pharmaceutical Officer subsequently urged PCTs and CCGs to review their local formulary processes in order to be compliant with these requirements by 1st April 2013.
   Member organisations confirmed that actions taken on their behalf by the North of Tyne APC were sufficient to satisfy their obligations with regards to this.

TD highlighted to the committee the requirement for all provider organisations to make this information available on their websites and that this is also a requirement within the NHS Standard Contract. NTW have done this by linking from their website to the North of Tyne APC website and he encouraged other provider organisations to consider their own processes in relation to these requirements.

2. ML/IC updated the committee on the progress with regards to an ongoing review of growth hormone products. Updated recommendations will be presented to the formulary subcommittee in due course.

2013/37 Date and time of next meeting

Tuesday 14th May 2013 at 12:30pm
Room 3 ,Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.

Signed: ..... **Date:** 14/5/13

(Chair of the APC)

North of Tyne
Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 12th March 2013.**

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				
Tadalafil – post radical prostatectomy				Tadalafil has been requested for penile rehabilitation (i.e. restoration of erectile function) after radical prostatectomy (RP). Erectile dysfunction occurs in 80% of patients following RP and can persist for as long as 24 months. The request was previously deferred pending receipt of further evidence for the use of twice weekly tadalafil in this indication, particularly around the number of patients who will regain normal erectile function. There was also request for clarification on whether there is potential for using sildenafil in this indication due to its forthcoming patent expiry in 2013. **Decision:** Application considered withdrawn as the applicant was not able to provide the previously requested information in time for this meeting.
Follitropin alfa (Gonal – F®)				Gonal F had been requested for inclusion in the Formulary as an additional treatment option to Menopur in IVF. It is available as a prefilled pen and it is anticipated that it will reduce wastage and improve patient compliance. At the previous FSC meeting, the request was deferred pending supporting audit data to support that wastage is reduced with Gonal F. **Decision:** Application considered withdrawn as the applicant was not able to provide the previously requested information in time for this meeting.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Palifermin				Palifermin is a recombinant form of human keratinocyte growth factor (KGF). It had been requested for the prevention of mucositis post HSCT in SCIDs (severe combined immune deficiency) patients. It is unlicensed for this indication and in children. In adult patients studies have shown that it prevents / decreases the severity of mucositis reducing the need for parenteral nutrition and opioids. Furthermore it may reduce the severity of acute Graft versus Host disease (aGvHD). There is no alternative preventative intervention for mucositis. **Decision:** Application considered withdrawn as the applicant was not able to provide the previously requested information in time for this meeting.
Botulinum Toxin A – Bladder dysfunction in paediatrics [u]			√	Botulinum toxin A is currently included in the Formulary (for adult patients) for the treatment of overactive bladders in patients who have failed to respond to conservative treatment. This is an unlicensed indication. It has now been requested for this indication in paediatric patients. **Bladder dysfunction** – deferred until data can be provided on whether treatment was successful for patients in whom this treatment has already been tried and the provision of a clear treatment pathway.
2) New Requests				
Ceftaroline	√ R			This 5th generation cephalosporin has been requested for use as an alternative to daptomycin or linezolid in patients with bacteraemia/cSSSI on the grounds that it does not cause bone marrow suppression or rises in creatinine kinase; it does not interact with SSRIs and other agents that act on the serotonergic system; and it is effective and well tolerated. **Decision:** The request for ceftaroline was approved. It will be a red drug and should be prescribed only on the advice of a microbiologist.
Eculizumab – paediatric heart transplantation [u]	See notes			Eculizumab has been requested for the prevention of acute cardiac rejection post-transplant. It was noted that while some evidence of efficacy in the reduction of antibody mediated rejection (AMR) has been demonstrated in kidney transplantation, the evidence of clinical effectiveness specifically in paediatric cardiac transplantation is limited. It was felt that the evidence of efficacy in the kidney transplantation might suggest proof of concept in that it would be efficacious in AMR in paediatric cardiac transplantation. **Decision**: The request for eculizumab in the prevention of AMR in paediatric heart transplantation should be referred to the Local Area Team of The NHS Commissioning Board. Until a national commissioning decision is taken this will be in the form of IFRs.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
3) New formulations & extensions to use				
Thalidomide - angiodysplasia [u]	√ R			Thalidomide has been requested for the treatment of bleeding from bowel angiodysplasia in patients with an inherited/acquired bleeding disorder. It was noted that this is an unlicensed indication and evidence is limited, but it was acknowledged that this is a difficult to treat condition and that, in patients where treatment was successful and tolerated, it would result in a large reduction in expenditure on blood factors. **Decision: Approved.** The request for thalidomide for angiodysplasia was approved.
ii) Forceval soluble	√			Forceval Soluble is a multi vitamin and mineral supplement which has been requested for short term use in patients who are unable to swallow Forceval capsules. This product is significantly more expensive than the Forceval capsules therefore the formulary subcommittee sought clarification as to whether Forceval Soluble has nutritional advantages over the alternatives. The inclusion of trace elements that are not included in other formulary approved products assured the committee of the need for this alternative preparation. **Decision: Approved.** The request for Forceval soluble was approved for short term use in patients who are unable to swallow Forceval capsules.
Plenadren (MR Hydrocortisone)		√		Plenadren is a modified release hydrocortisone preparation that has been designed to more closely mimic the natural circadian rhythm compared to the immediate release preparation. It has been requested for the treatment of adrenal insufficiency in patients with co-existing diabetes, with brittle control or poor compliance. It was noted that whilst there is evidence of some improvements in glycaemic control the clinical significance changes were unclear and that the number of diabetic patients in the study was low. **Decision: Refused.** The request for Plenadren was not approved. The committee was not convinced that the level of effectiveness demonstrated justified the high costs.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Clopidogrel suspension 75mg/ml	√ R			Requested for use in paediatric patients who are unable to swallow tablets. It was noted that the suspension is 100 times more expensive than the tablet formulation; however the difficulties in ensuring the correct dose is given if the tablets are crushed were acknowledged. **Decision: Approved.** Approved for hospital use in children on Berlin Heart Devices.
Warfarin suspension 1mg/ml			√	Requested for paediatric patients on mechanical support using ventricular assistance devices, and for paediatric patients with mechanical heart valves or irregular heart rhythms who are unable to swallow tablets. It was noted that the suspension is 50 times more expensive than the tablet formulation. **Decision: Deferred** The Subcommittee has asked for data to be provided that the current practice of crushing warfarin tablets leads to paediatric patients being out range for longer than is acceptable.
Alendronic acid solution		√		**Decision: Refused.**
4) Products considered by NECDAG and decisions endorsed by APC				
Abiraterone for metatstic castration resistant prostate cancer (chemotherapy naive)				NECDAG – Considered 28.11.12 – Unable to fund through normal route due to lack of evidence of cost effectiveness therefore considered for CDF. Rejected from Standard NHS Funding Approved from Cancer Drug Fund: • Following MHRA confirmation of its safety and efficacy in this indication by granting abiraterone a product licence for this indication (Dec 2012) • Provided the following 'stopping rules' are followed where there is a borderline evidence of benefit: STOP if - Clinical progression including the need for palliative RT - PSA progression supported by radiology (if the PSA rise >25% above baseline and/or 3 consecutive rises then a repeat bone scan +/- CT scan should be arranged). Note this approval is subject to ongoing review of priorities and along with all CDF approvals will be reviewed for 2013/14.
5) Products considered by NETAG and decisions endorsed by APC				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Anti-thymocyte globulin for first-line treatment of adult aplastic anaemia	√			The NHS North East Treatment Advisory Group recommends horse ATG as first-line immunosuppressive therapy in preference to rabbit ATG for the treatment of adult aplastic anaemia.
Ulipristal (ellaOne®) for post-coital contraception: Updated appraisal	See notes			The NHS North East Treatment Advisory Group has not opted to change its previous recommendation following an updated appraisal of ulipristal (ellaOne®) for post-coital contraception. The group does not recommend ulipristal for any specific patient groups: **Ulipristal (ellaOne®) is 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.** When considering ulipristal, patients should be advised of the requirement for additional barrier contraception until their next menstrual period, its unknown teratogenic effects, and its common adverse effects such as menstrual delay and gastro-intestinal effects.
Aflibercept (Eylea®) for neovascular age-related macular degeneration	√ See notes			The NHS North East Treatment Advisory Group recommends aflibercept (Eylea®) within its licensed indication for the treatment of newly diagnosed and untreated neovascular (wet) age-related macular degeneration. The group does not recommend aflibercept for the same episode of AMD refractory to treatment with other biological therapies such as ranibizumab. This recommendation is contingent on a maximum cost per aflibercept dose as stated in the associated appraisal report.
6) Products considered by NESCG and decisions endorsed by APC				
None				
7) Products considered by NICE				
TA271: Diabetic macular oedema - fluocinolone acetonide intravitreal implant	√			Approved in line with NICE TAG

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA272 : Urothelial tract carcinoma (transitional cell, advanced, metastatic) – vinflunine	√			Approved in line with NICE TAG.
TA273 : Hyperplasia (benign prostatic) - tadalafil (terminated appraisal)				Termination of appraisal noted.
TA 274: Macular oedema(diabetic) – ranibizumab	√			Approved in line with NICE TAG.
TA275: Stroke and systemic embolism (prevention, non-valvular atrial fibrillation) - apixaban	√			Approved in line with NICE TAG.
8) Appeals against earlier decisions by the APC				
Fluticasone & Formoterol (Flutiform®) 50mcg/5mcg 125mcg/5mcg 250mcg/10mcg	√			Flutiform had been requested for the maintenance treatment of asthma. This application was refused in January as, whilst it was appreciated that there was a potential for some cost savings at higher doses, it was anticipated that this cost advantage was not large. **Decision: Approved (for asthma).** Additional financial information presented to the committee was sufficient to overturn the original decision. The committee approved the use for maintenance treatment of asthma in line with licensed indications.
Cefixime [u]	√			Requested to prevent irinotecan related diarrhoea. **Decision: Approved** Additional information presented to the committee was sufficient to overturn the original decision.
9) Miscellaneous decisions by the APC				
Darunavir 800mg tablets	√			Darunavir is now available as an 800mg tablet; the cost is pro rata. **Decision: Approved** Darunavir 800mg tablets should be added to the Formulary.
Testosterone 100mg and 200mg implants				Discontinued by the manufacturer. Sachets, patches and injections are still available. **Decision: Approved** The Formulary will be updated to reflect the change.
Tretinoin gel (Retin A)	√			Discontinued by the manufacturer. Adapalene is being used instead of isotretinoin. **Decision: Approved** The Formulary will be updated to reflect the change.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Dornase alfa - traffic light status from red to blue				There has been a request to have dornase alfa changed from a red to blue drug to avoid patients having to attend hospital. There are no specific monitoring requirements or safety issues. **Decision: Approved** The committee agreed that it is clinically appropriate for GPs to prescribe dornase alfa.
Nicotinic acid/laropiprant (Tredaptive)				Discontinued by the manufacturer. The Formulary will be updated to reflect the change.