North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 10th July 2012 at Northumbria House, Cobalt Business Park, North Tyneside

Present

David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Neil Watson	Clinical Director of Pharmacy and Medicines Management	NUTH
Susan Turner (STu) (Professional Secretary)	Medicines Management Advisor	NHS NoT
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Alexander Dyker		NUTH
Rosie England (RE)	Associate Director of Medicines Management	NHS NoT
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Sue Dickinson (SD)	Director of Pharmacy	RDTC
Ian Campbell	Assistant Director of Pharmacy	NUTH
Sue Gordon	Executive Director Public Health	NHS NoT
Janet Kelly (JK)	Nurse Clinical Manager	NNTCH
Peter McEvedy	GP and Prescribing lead Northumberland CCG	
Zahra Irranejad	Head of Prescribing (Provider)	North of Tyne PCTs
Matthew Grove	Consultant Rheumatologist, NTGH	NHCT
Tamsin Oswald	Consultant Microbiologist	NHCT
Helen Coundon (HC)	GP representative from Engage Clinical Commissioning Group	
Simon Thomas (ST)	Consultant Clinical Pharmacologist	NUTH

In Attendance

Dr David Spencer
Dr Stephen Bourke

Apologies

Mark Burdon	Community Pharmacy Representative	NoT LPC
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NECN
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH
Amy Gall	GP representative from Newcastle North and East CCG	
Matthew Lowery (ML)	Formulary and Audit Pharmacist	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
NNTCH	Newcastle, North Tyneside Community Health Services
NTWT	Northumberland Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre

Membership update
Dr Gordon Pearston has resigned from the committee and Dr Amy Gall will represent NHS Newcastle North and East CCG.

2012/48 Declarations of interest
No declarations were made.
Committee members were asked to complete the Annual Declarations of interest form and return this directly to the Professional Secretary.

2012/49 Appeals

Tobi Podhaler
On 8th May 2012 the APC approved an application to have the above product available for use within the North of Tyne area but restricted this approval to short term use of no longer than 2 weeks and stated that TOBI Podhaler was not approved for chronic therapy instead of nebulised therapy.
The applicant appealed this restriction and Dr David Spencer attended to present the appeal. Through his presentation and prior written submission attention was drawn to the following points:

- TOBI Podhaler is indicated for the suppressive therapy of chronic pulmonary infection due to *Pseudomonas aeruginosa* in adults and children aged 6 years and older with cystic fibrosis.
- Short term use of no longer than 2 weeks is not the intended or licensed used for this product. The recommended dose is 112mg inhaled bd in alternating 28 days on treatment and 28 days off treatment.
- Two clinical trials have demonstrated the clinical efficacy of TIP when compared to placebo and Tobramycin Solution for Inhalation aka TSI (current nebulised product).
- The current alternative products for patients with CF are all delivered via a nebuliser. Wet nebulisers may become a source of bacterial infection and contamination of the home equipment with bacterial pathogens after suboptimal cleaning procedures is recognised. This potential problem with contamination will not be encountered by using TIP as the device is disposable after 1 week's use.
- The cost of TIP is now in line with its cheapest alternative – Bramitob. In addition to the cost of TSI the cost of a nebuliser and its associated sundries is not insignificant.
- A policy for the use of inhaled antibiotics has been developed through the National Specialist Commissioning Group. This was prepared prior to the introduction of TIP and does not address this specifically but it was stated that the general principles outlined within it remain appropriate and the following sections from that were highlighted:
    - It is recommended that all patients with evidence of chronic Pseudomonas infection should receive therapy with nebulised/inhaled anti-Pseudomonas antibiotic
    - In some patients, adherence to treatment may be improved if prescribed as a month on/month off treatment regimen of inhaled tobramycin twice daily before being able to maintain a chronic daily regimen.
    - A stepwise approach should be used where Colistin is used first line

when pulmonary function is normal but chronic Pseudomonas infection is evident and tobramycin should be considered if, despite continued therapy and good adherence to treatment, lung function continues to decline or there is a requirement for more than one course of iv antibiotics in the preceding year. This may be prescribed alternate months in conjunction with Colistin.

- Treatment should be initiated and, where appropriate, escalated with the least expensive suitable product.

Dr Spencer confirmed that clinicians would continue to prescribe Colomycin as a first line treatment in patients but would use TIP as a sensible option for second line treatment

- The use of TIP in place of TSI offers a significant improvement to patients in terms of the time taken to prepare the medication, administer the drug and clean the nebuliser device.
- TIP will not be given to every patient in keeping with the use of Tobramycin as a second-line agent currently. However in patients in whom use of Tobramycin is being considered it is felt that they should be offered the full range of options available in order that the best outcomes are achieved
- TIP has been approved for use in other areas of the country (Leeds, Liverpool, London and Cambridge) and it has recently been approved for use by the Scottish Medicines consortium.

On reflection the committee decided that the appeal would be upheld.

Decision: Approved

Tobramycin Inhalation Powder (TOBI Podhaler®) was approved for second line use after Colomycin subject to cost neutrality with the competing product. This decision will be reviewed if the market changes significantly. It will remain a RED drug

Indacaterol – Dr Stephen Bourke presented the appeal. The following points were noted:

- In COPD, for various outcomes including quality of life and FEV1, bronchodilators often achieve the minimum clinically important difference (MCID) by a narrow margin and most do not consistently achieve the MCID for all outcomes.
- For new agents achieving the MCID compared to placebo is a reasonable minimum standard. Within a class, however, improvements tend to be incremental and achieving the MCID not only over placebo, but also over established agents within the same class is unlikely to be achieved.

A recent DTB review highlighted that for various outcomes indacaterol achieved the MCID over placebo, but superior performance compared to other long acting bronchodilators fell short of the MCID. Dr Bourke acknowledged this article but wished the committee to consider the following :

- Compared to other long acting bronchodilators, including Tiotropium and other LABAs, most clinical outcomes consistently favoured

indacaterol (statistically) and where this was not achieved, outcomes were at least equivalent.
- With regard to MCID: In RCTs comparing indacaterol and alternative long acting bronchodilators to placebo, for some clinically relevant outcomes, the MCID compared to placebo was only achieved for indacaterol.
- For several outcomes, compared to alternative agents, a significantly higher proportion of patients achieved the MCID in the indacaterol arm.

It was pointed out that with inhaled therapy, the device is of great importance and there is considerable variation between patients with regard to inhaler technique and preference. Occasionally patients are not certain whether or not they have inhaled active drug following use of their device. Where this is a concern, one advantage of the Breezhaler is that the capsule is transparent therefore the patient can see that they have received the full dose. A wider choice of device can therefore be helpful.

The committee had also previously been supplied with the results of pooled analyses for exacerbations compared to placebo and SGRQ and Breathlessness (TDI) compared to tiotropium and placebo presented at the COPD 8 conference and had considered these.

The committee asked whether there was peer support for the application and noted that there appeared to be widespread support for the application from clinicians and clinical groups across the North of Tyne area although it was noted that there had not been commissioning involvement during the development of local COPD guidelines that incorporated this product.

The committee was aware that Novartis had submitted a commercial in confidence agreement to try and alleviate any concerns over additional costs that may be associated with the use of this product and Dr Bourke also indicated that reductions in price in inhaler devices when they come off patent are not as great as with other medications.

The committee on reflection however still felt there was not enough clinical benefit demonstrated to justify the risk in cost pressure that would be associated with use of this product.

Decision: Refused

2012/50 Minutes and decision summary from the meeting held on Tuesday 8th May 2012.

These were accepted as a true record.

2012/51 Matters arising

2012/37 Dovobet Gel

An application to have Dovobet Gel included in the North of Tyne Formulary was considered on 8th May. At that point the committee was minded to accept the application, but there was concern over the potential for inappropriate use. The applicant was asked to submit an algorithm to the APC showing the appropriate place in therapy, advice on short-term use and the recommended rotation

between calcipotriol alone, calcipotriol with steroid and emulsifying products. This information was received and considered by the committee. The product was approved for use.
The information provided will be made available to prescribers subject to minor amendments including the reconsideration of the position of Tar Pomade within suggested treatment regimens and the inclusion of recommendations relating to suggested timescales and frequency of treatment cycles.

Decision: Approved

2012/52 Report from the Formulary Sub-committee

Minutes and recommendations from the meeting held on Tuesday 26th June 2012.
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 point was highlighted:

Lidocaine 4%, adrenaline 0.1% & tetracaine 0.5% (LAT® gel) [u]

LAT gel has been requested to replace 1% lidocaine for use in anaesthetising lacerations <4cm in length, particularly in the paediatric population, on the grounds that it is less painful than infiltration of local anaesthetic. Concerns were expressed at the formulary subcommittee meeting regarding the recommended maximum dose, given that a 3ml dose in children <15kg would exceed the maximum recommended IV dose for lidocaine when used alone. The committee therefore deferred their decision until further clarification was sought. This has since been done and an algorithm will be produced that ensures the gel will not be used in children under 15kg without appropriate dose adjustment.

Decision: Approved.
Lidocaine 4%, adrenaline 0.1% & tetracaine 0.5% (LAT® gel) [u] was approved subject to the development of an algorithm which will ensure that LAT will not be used in children under 15kg without appropriate dose adjustment.

Subject to the above, all other recommendations were endorsed by the committee and will be reflected in the North of Tyne Formulary.

The committee were advised that Formulary Version 3.7 is now available on the website.

2012/53 Report from the Shared Care Group (SCG).

Version 3.4 (May 2012) of the traffic light list is now available on the website.

Unapproved minutes from the meeting of 13/6/12 were received.
Sarah Chandler highlighted the following points to the committee:

- Updated request/confirmation form – this was approved and will be incorporated into all guidelines.
- Dronedarone SCG – the Shared Care Guideline for Dronedarone was approved. This had been prepared to give governance support to GPs who were currently prescribing this product or prepared to do so. It was noted,

however, that this is at present un-commissioned work therefore any 'shared care' arrangements must be put in place through discussion and agreement with individual GPs and not by assumption that because there is a documented pathway that this work must be taken on by GPs. As part of the dissemination process there will need to be clear communication with hospital consultants regarding this.

- Withdrawal from Shared Care – A document for GPs to use if intending to withdraw from a shared care agreement had been circulated to APC members in May (Agenda item 2012/38). Following comments from the APC the Shared Care Group have resubmitted this for approval and stressed that the form is only intended for use in relatively few situations and always following dialogue with the initiating physician. The APC considered these points but does not endorse the use of such a document as it is felt to be counter to constructive dialogue between clinicians.

It was suggested that the minutes from the SCG may be interpreted to suggest that member CCGs may come to different decisions relating to approval of guidelines. The committee stressed that TORs of the APC and all subgroups need to reflect that members agree to be bound by decisions of the group. Duplication of work and variance in decisions across the area are not sustainable.

2012/54 Report from the Anti-microbial Chemotherapy subcommittee.

Unapproved minutes from the meeting of 25/4/12 were received.
Tamsin Oswald was welcomed to the committee as a new member and presented the primary care guidelines which were approved subject to minor alteration including:

1. An attached summary of key changes since the last version
2. A note about how expensive certain syrups/suspensions are
3. A note in the UTI section about **NOT** prescribing the 50mg nitrofurantoin tablets due to the cost.

These guidelines need to be easily accessible for all in primary care. They will be available on the APC website and sent to all medicines managers. Individual members take responsibility for further dissemination within their organisation.

The revised ToRs were not available to circulate but will be forwarded to the secretary for distribution along with the amended guidelines.

2012/55 Quality, Improvement, Productivity and Performance (QIPP)
Minutes from the meeting held on 18/4/12 were received along with unapproved minutes from the meeting held on 20/6/12.
RE highlighted the following :

- The report for April 2012 projected a total saving at the end of the 2011/12 financial year of £1,108,771 for work facilitated through this group. However, ePACT data for this period has demonstrated an increase of 6% on this figure with a total saving of £1,174,936 realised and 19,571 patients treatment changed or reviewed.
- The most notable increase in savings has been seen for Venlafaxine with a total saving over the financial year of £232,900.

2012/56 Sip Feeds Formulary

This was received and approved by the committee. The contents will be incorporated into the North of Tyne Formulary.

2012/57 Prescribing Outwith Licence

The committee had been asked to issue a statement relating to off-label prescribing in response to community pharmacy requests to GPs to either prescribe pioglitazone by brand or to confirm in writing that when a generic product was prescribed in combination with metformin they were aware that such products did not have a licence to cover this use.

The committee recognise that this is a complicated issue, with the GMC having delayed their anticipated updated advice in response to an ongoing legal challenge.

The APC has previously issued guidance, available on their website relating to branded vs generic prescribing in the document **"Medicines that are Not Suitable for Generic Prescribing – March 2012"** which states:

Prescribing medicines generically rather than by brand name can improve cost-effectiveness and is encouraged. However, there are some circumstances in which brand-name prescribing is preferred. These include:

- Where there is a clinically important difference in bioavailability between brands of the same medicine, particularly if the medicine has a narrow therapeutic index.
- Where modified release preparations are not interchangeable.
- Where there are important differences in formulation between brands of the same medicine.
- Where products contain multiple ingredients and brand name prescribing aids identification.
- Where administration devices (e.g. inhaler or self-injection) have different instructions for use and patient familiarity with the same product is important.

Pioglitazone does not fall into any of the above categories.

The APC stands by the principle of generic prescribing.

2012/58 Annual Report

This was approved by the committee subject to the inclusion of the QIPP savings outlined in item 2012/55 being incorporated into the document. The secretary will send the approved report to the chief executives of member organisations and to each CCG

2012/59 Documents previously circulated by email

- NECDAG Minutes – 30/5/12
- Interim Cancer Drug Fund (ICDF) Decision Document - Cetuximab (Erbitux) for Metastatic Colorectal Cancer (CRC)
- Cancer Drug Fund Decision Document – Sorafenib in thyroid cancer
- Cancer Drug Fund Decision Document – SIRT (Selective internal radiation therapy) in colorectal liver metastasis
- Cancer Drug Fund Decision Document – Fulvestrant (Faslodex) in 3rd or later line metastatic breast cancer

The above documents were noted and the recommendations endorsed by the APC. Amendments will be made to the formulary where necessary.

- MSD letter

Several members of the committee and Formulary Subcommittee have received a letter from the medical director of MSD asking them to reconsider the decision to make saxagliptin the DPPIV inhibitor of choice in this area.
The chairman had replied on behalf of these members stating that the committee would discuss the letter at the July meeting and that such discussions would be made public by means of the minutes of that meeting.
The committee feels that decisions relating to formulary recommendations are taken after full consideration of all relevant information and are satisfied that the processes in place, and applied to each application, are robust. This process had been applied to the choice of DPPIV inhibitor for formulary inclusion.

2012/60 APC Guidelines and Statements for review

None received

2012/61 Terms of Reference

The current terms of reference have been reviewed for 2012-13. It is recognised that the changing NHS organisational structures will require this to be repeated for 2013-14 but in the meantime the draft update will be circulated by DCa to members and CCG leads for comment.
Paediatric representation has been sought for the committee but no nominations have been received. TD, DC and NW agreed to approach appropriate clinicians within their organisations regarding this.

2012/62 NICE

Boceprevir and telaprevir were approved for use at the March 2012 meeting on the proviso that the approval would be reviewed on publication of the NICE TAGs. The following NICE TAs have now been published and use of these products in the North of Tyne Area will reflect these.

- TA252 - Telaprevir for the treatment of genotype 1 chronic hepatitis C
- TA253 - Boceprevir for the treatment of genotype 1 chronic hepatitis C

The following NICE TAs were also endorsed by the committee for use in the North of Tyne Area.

- TA254 - Fingolimod for the treatment of highly active relapsing–remitting multiple sclerosis
- TA255 - Cabazitaxel for hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen
- TA256 - Rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation. It was noted that Dr. Skinner is holding a meeting at which she hopes to achieve a consensus on the positioning of rivaroxaban and dabigatran in the Formulary for AF.
- TA257 - Breast cancer (metastatic hormone-receptor) - lapatinib and trastuzumab (with aromatase inhibitor)
- TA258 - Lung cancer (non small cell, EGFR-TK mutation positive) - erlotinib (1st line)
- TA259 - Prostate cancer (metastatic, castration resistant) - abiraterone (following cytoxic therapy)
- TA260 - Migraine (chronic) - botulinum toxin type A

Recently published NICE TAGs will in future be considered as a standing agenda item at each meeting.

CG140: Opioids in palliative care

The FSC minutes noted that the above guideline includes buprenorphine patches

as a treatment option as well as fentanyl patches. A previous application for buprenorphine patches was refused by the APC. Indications have been given that a new application for these may now be submitted.

2012/63 Chair's action

- **Alfentanil**
  DC informed the committee that he had approved the addition of this to the North of Tyne Formulary in line with the NECN Palliative care guidelines. It would be for specialist initiation only.

2012/64 Any other business

2012/65 Date and time of next meeting

Date and time of next meeting:
Tuesday 11th September
Room 2 and 3 ,Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.
The meeting will start at 12:30pm

Signed: ..... **Date:** 11/9/12
(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 10th July 2012.**

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: Approved	Decision: Refused	Decision: Deferred	Comments/notes
1) Requests deferred from previous meetings				
Fentanyl citrate (Abstral®)		√		Abstral had been requested for breakthrough pain relief for patients undergoing radiotherapy, who have difficulty swallowing/ cannot swallow and are experiencing grade 3+ mucositis. Further information regarding evidence of efficacy, clarity on how patients in the target group are fed, and how analgesia is currently administered to this group had been sought. Confirmation was received that these patients often have feeding tubes, but there was a suggestion that the administration of analgesia via this method is unreliable. There is no evidence in the specialist reference sources to support this claim. **Decision: Refused**
Intranasal midazolam[u]	√ R			Intranasal midazolam 40mg/ml + lidocaine 20mg/ml (0.5ml ampoules) has been requested for use prior to cannulation for adult patients with special needs receiving dental treatment under IV sedation. In 2008, the NPSA released an alert for high strength midazolam injection. In light of the NPSA alert the committee agreed that further information was required to justify the strength being requested and due to the risks of having stocks of the 20mg ampoules in the clinical area, requested that a risk assessment be undertaken. This risk assessment had been now been undertaken and an SOP is now in place specifying that only two named clinicians can use intranasal midazolam and that the intranasal midazolam will be kept in a separate cupboard from the IV midazolam. **Decision:** The request was approved. Intranasal midazolam will be classified as a red drug. In addition it should be added to the Dental Hospital's risk register.
Dovobet® gel	√			**Decision: Approved** A supporting leaflet that will aid prescribers with the intended position in therapy compared with other available products, how use can be kept to within the licensed duration(s) and how often treatment would be expected to be repeated will be made available.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
AdCal D_3® caplets			√	Additional information relating to dosing and compliance was requested before a decision could be made. They were claimed to be considerably easier to take in comparison with existing products but as opposed to one tablet once daily, the equivalent dose is two caplets twice daily. It was reported that the savings that might be made by using AdCal D_3 caplets were not as great as had been suggested **Decision:** A review of this entire section of the Formulary should be conducted with the findings to be reported at the next meeting of the Formulary Subcommittee.
2) New Requests				
Lidocaine 4%, adrenaline 0.1% & tetracaine 0.5% (LAT® gel) [u]	√			LAT gel has been requested to replace 1% lidocaine for use in anaesthetising lacerations <4cm in length, particularly in the paediatric population, on the grounds that it is less painful than infiltration of local anaesthetic. The limited evidence suggests that the anaesthetic affect produced appears to be similar to 1% lidocaine for infiltration. Topical anaesthetic does not cause tissue distortion, which is common with an injection, and using LAT gel will reduce the risk of needle injuries. Use will reduce the number of patients being admitted for suturing under general anaesthetic. Concerns were expressed regarding the recommended maximum dose, given that a 3ml dose in children <15kg would exceed the maximum recommended IV dose for lidocaine when used alone. **Decision:** Approved subject to the development of an algorithm which will ensure that LAT will not be used in children under 15kg without appropriate dose adjustment.
Regadenoson	√			Regadenoson is a myocardial perfusion imaging agent that has been requested for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress; • for patients with COPD and asthma where dobutamine is indicated; • for obese patients who require several vials of adenosine. It is administered as a rapid IV bolus as opposed to a 4 minute infusion for adenosine and 15 minutes for dobutamine. The dose of regadenoson is not dose dependant and, unlike adenosine, it is not contraindicated in patients with asthma and COPD. Any increase in drug costs will be offset by savings in consultant time. **Decision:** The application for Regadenoson was approved.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Viscous budesonide [u]	√ R			Oral viscous budesonide has been requested for the treatment of eosinophilic oesophagitis. Topical corticosteroids such as fluticasone (delivered via an inhaler) are a treatment option. Oral viscous budesonide is a liquid consisting of budesonide nebuliser solution mixed with syrup. There is some evidence that budesonide can reverse oesophageal fibrosis. It was noted that this treatment has to be mixed immediately before use and that the cost difference between oral viscous budesonide and fluticasone is minimal, however the ease of administration , particularly in children, was felt to be a significant advantage **Decision:** The request for oral viscous budesonide was approved. It will be classified as a Red drug.
Hyalofemme®		√		This vaginal moisturiser has been requested for the relief of symptoms of atrophic vaginitis, particularly in women who have had treatment for gynaecological malignancy (radiotherapy). It is classified as a class II medical device. Currently the only option available for this group of patients is lubricating gel. Lubricating gel is felt to be inferior as it has no moisturising properties. Hyalofemme is the cheapest vaginal moisturiser available. It was noted that there is little evidence of efficacy and that this product is relatively expensive. It is available to buy over the counter. **Decsion:** The request was refused.
Anidulafungin	√			Anidulafungin has been requested for the treatment of invasive candidiasis in adult non neutropenic patients. It has no drug interactions, unlike caspofungin and micafungin, and similarly does not require dose adjustment in renal and hepatic impairment. Anidulafungin has a similar spectrum of activity to the other echinocandins and it is relatively well tolerated with a relatively low risk of leading to elevated hepatic enzymes. It is superior to fluconazole for invasive candidal infections in non-neutropenic patients. **Decision:** The request was approved. The committee requested clarification to be sought on whether it was necessary to retain Micafungin on the Formulary to treat resistant cases.
Citrasate	√			Citrasate has been requested for use in place of standard dialysate formulations for patients in whom anticoagulation is problematic or contraindicated. It is a sodium citrate based dialysate with a citrate concentration of 0.8mmol/L. This is enough to provide a local anticoagulant effect at the dialyser membrane but is lower than the concentration required in the blood to achieve anticoagulation **Decision:** The request was approved.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Primsocitrate 18/0 & PrimsOcal B22	√			Prismocitrate 18/0 and Prism0cal B22 have been requested for regional anticoagulation using citrate in continuous renal replacement therapies (CRRT). This is on the grounds that regional citrate anticoagulation is safer than systemic anticoagulation with heparin in patients at high risk of bleeding. This will be used in all patients requiring CRRT to ensure that all nursing staff are familiar with the technique, therefore increasing patient safety. **Decision:** The request for Prismocitrate/Prism0cal was approved.
3) New formulations & extensions to use				
Pregabalin – General anxiety disorder	√			Pregabalin is recommended by NICE as a 2nd line agent for General Anxiety Disorder It was noted that pregabalin is already widely prescribed by GPs for other conditions. It was discussed that although treatment can be given as a maximum dose of up to 600mg daily in 2 – 3 divided doses, it is more cost effective to give as a twice daily dose. **Decision:** Pregabalin will be added to the Formulary according to NICE guidelines, but a dose of twice daily should be prescribed as opposed to three times daily.
4) Products considered by NECDAG				
Cetuximab (Erbitux) for Metastatic Colorectal Cancer (CRC)	√ Approved from Cancer Drug Fund 30.5 2012			In 2012 NICE reviewed cetuximab in the second/third line setting and concluded that the treatment was not cost effective and should not be funded from standard NHS funding. NECDAG suspended NHS funding pending this review. **Interim Cancer Drug Fund (ICDF) Decision -** Approved from Cancer Drug Fund 30.5.2012
Sorafenib in thyroid cancer	√ Approved from Cancer Drug Fund 30th May 2012 (subject to ongoing review)			NECDAG considered an application in November 2010, but was unable to grant approval at the time due to an open Phase III clinical trial and lack of Phase III data. Rejected from Standard NHS funding. **Cancer Drug Fund Decision** Approved from Cancer Drug Fund 30th May 2012 (subject to ongoing review)

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
SIRT (Selective internal radiation therapy) in colorectal liver metastasis	See notes			NICE has previously reviewed the clinical effectiveness of SIRT in Colorectal Cancer in an Interventional Procedure Guidance (IPG401) which is not mandatory and does not consider cost-effectiveness of the approach. No guidance has previously been issued from NECDAG with this regard. NICE recommended further research and on-going audit. **Cancer Drug Fund Decision** Rejected from Standard NHS funding NECDAG agreed to fund a maximum of 20 patients per year from the Cancer Drug Fund for SIRT who met the criteria above. To continue funding the outcomes from the first 15 patients must be presented to NECDAG.
Fulvestrant (Faslodex) in 3rd or later line metastatic breast cancer	See notes			In 2012 NICE reviewed this treatment in a first/second line setting and concluded that the treatment was not cost effective (treatment after second line was out of scope). NECDAG suspended funding pending this review. NECDAG has now concluded that this treatment is unlikely to be a cost effective from use of Standard NHS funding **Cancer Drug Fund Decision** Approved from Cancer Drug Fund on 30th May 2012 for a limited period to allow audit data from existing patients to be collated and reported to NECDAG in September. The decision will be reviewed in light of the audit data.

5) Products considered by NETAG

None received				

6) Products considered by NICE

The following NICE TAGS were endorsed by the committee for use in the North of Tyne area:

- TA252 – Hepatitis C (Genotype 1) - Telaprevir
- TA253 – Hepatitis C (Genotype 1) -Boceprevir
- TA254 – Multiple Sclerosis (relapsing – remitting) - Fingolimod
- TA255 – Prostate Cancer - Cabazitaxel
- TA256 – Atrial Fibrillation (Stroke Prevention) - Rivaroxaban
- TA257 - Breast cancer (metastatic hormone-receptor) - Lapatinib and Trastuzumab (with aromatase inhibitor)
- TA258 - Lung cancer (non small cell, EGFR-TK mutation positive) - Erlotinib (1st line)
- TA260 - Migraine (chronic) - Botulinum toxin type A
- TA259 - Prostate cancer (metastatic, castration resistant) - Abiraterone (following cytoxic therapy)

7) Appeals against earlier decisions by the APC

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TOBI Podhaler®	√			**TOBI Podhaler®** had previously been approved for short term use for courses of no longer than two weeks. It was not accepted for chronic therapy instead of nebulised therapy. Further information was subsequently provided. **Decision: Approved** for second line use after Colomycin subject to cost neutrality with the competing product. This decision will be reviewed if the market changes significantly.
Indacaterol (Onbrez Breezhaler®)		√		The committee previously refused the application for indacaterol on the grounds that the clinical advantages are limited and that the lack of a combination product is a disadvantage. There was also a concern that indacaterol would be less cost effective than salmeterol now that the patent for salmeterol has expired. Following the appeal the committee felt there was still not enough clinical benefit demonstrated to justify the risk in cost pressure that would be associated with use of this product. **Decision: Refused**
8) Miscellaneous decisions by the APC				
Rimexolone	See notes			The traffic light status of rimexolone has been reviewed and has been changed from Red, Hospital Use only, to specialist initiation.
Rufinamide suspension	√			Rufinamide tablets are included in the Formulary for use as a 2nd or 3rd line treatment in patients with Lennox-Gastaut syndrome and related encephalopathies. The suspension has been requested for use in patients who are unable to tolerate the tablets (paediatrics). **Decision:** Rufinamide suspension will be included in the Formulary.
Interferon 20mcg (Rebidose®)	√			Rebidose is a single use prefilled injection pen, as opposed to cartridges and prefilled syringes that are used in the vast majority of patients. Rebidose is recommended only when the cartridges and prefilled syringes are unsuitable; they are available in the same range of sizes as the pre-filled pens and are cost neutral. **Decision:** Rebidose will be included in the Formulary.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Colecalciferol 20,000iu	See notes			The committee was informed that there is now a UK produced, unlicensed, 20,000iu colecalciferol product, called Bio Vitamin D3, that contains an information sheet in English. Quality assurance checks have been undertaken by NUTH and it is of suitable quality. Therefore it can be used in preference to the imported (licensed in Germany) Dekristol product. It also has the advantage that it does not contain arachis oil and is cheaper than Dekristol. It was also noted that there may soon be a licensed 10,000iu colecalciferol product available. **Decision:** Bio Vitamin D3 20,000iu (unlicensed) will be added to the Formulary alongside Dekristol. This will be reviewed on confirmation of the availability of a licensed 10,000 unit product