North of Tyne
Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 13th March 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
Rosie England (RE)	Associate Director of Medicines Management	NHS NoT
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Sue Brent (SB)	Director of Pharmacy	RDTC
Ian Campbell	Assistant Director of Pharmacy	NUTH
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Peter McEvedy	GP representative from Northumberland Clinical Commissioning Group	
Matthew Grove	Consultant Rheumatologist, NTGH	NHCT
Helen Coundon (HC)	GP representative from Engage Clinical Commissioning Group	
Simon Thomas (ST)	Consultant Clinical Pharmacologist	NUTH
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NECN
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Zahra Irranejad	Head of Prescribing (Provider)	North of Tyne PCTs
Janet Kelly (JK)	Nurse Clinical Manager	NNTCH
Sue Gordon (SG)	Executive Director of Public Health	NHS NoT

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

In Attendance

Dr Gillian Hawthorne

2012/18 Sitagliptin Appeal

David Campbell welcomed Dr Gillian Hawthorne to the meeting and outlined the process for hearing the appeal.
Sitagliptin was previously approved for use in the North of Tyne area in November 2008. Following an application for saxagliptin to be added to the formulary (May 2011) the APC endorsed the decision that Saxagliptin would be the DPPIV peptidase inhibitor to be used for new patients. Sitagliptin was to be kept for existing patients only with a view to subsequently removing this product from the Formulary.
A new application to have sitagliptin reinstated on the formulary was received but this application was rejected by the APC in January 2012.
This decision has been appealed by Dr Hawthorne.
Dr Hawthorne thanked the committee for the opportunity to present the appeal in person and outlined the following points:

- Sitagliptin is the oldest of the DPPIV peptidase inhibitors and as such specialists have more experience in prescribing this drug.
- Sitagliptin has an older and more established safety base than saxagliptin.
- Saxagliptin was requested on the grounds of an extended license that allowed use in patients with a reduced eGFR - sitagliptin now has a license for use in patients with reduced kidney function as well.
- Addition of sitagliptin to the formulary would allow clinicians choice in the use of DPPIV peptidase inhibitors and enable them to gain more experience in the relative benefits of one over the other
- Choice within class allows for a quicker response to any safety concerns that may arise as experience is gained with newer agents.
- Sitagliptin appears to now be demonstrating a greater clinical benefit than was evident in pre-clinical data
- Evidence is now emerging of sustained glucose lowering at 2 years

The committee requested clarification relating to:

- The relative benefits of one agent over the other.
- Whether one was better tolerated than the other.
- Their place in therapy in relation to each other.
- Clarification that support for two DPPIV peptidase inhibitors was endorsed by clinicians across the North of Tyne area.

Dr Hawthorne outlined that:

- Historically choice would have been based on renal function, with saxagliptin having a license for use in patients with a reduced renal function. Sitagliptin also now has a license for use in this group of patients.
- Each drug has a slightly different specificity and this may translate into different use as experience is gained with each.
- There is an argument that sitagliptin has a better renal profile now but more experience with use of both products would be needed to verify this.
- Clinicians in this area have demonstrated responsible use of newer agents in diabetes treatments as evidenced by our rates of insulin analogue prescribing.

The committee reviewed the data presented and the points raised for the appeal along with the original evidence submitted. The committee did not feel that there was a need for two agents within this class and did not feel there had been enough evidence presented to persuade it to reverse its original decision not to approve the use of this drug.
It was agreed that the committee would review the relative benefits of one DPPIV peptidase inhibitor over another as more products, and evidence relating to their relative benefits, became available.

Decision: The original decision relating to sitagliptin stands. The application to have sitagliptin reinstated to the formulary was refused.

2012/19 Declarations of interest

The chairman has asked that this should be included as a standing item on the agenda. Discussion took place as to what constituted a conflict of interest and hence should be declared.
Reference was made to nationally available documents including the NPC diagnostic tool and guidance issued by NICE.
It was agreed that these would be consulted for guidance.
In the meantime, members were asked to declare any personal interests they felt could be considered as a conflict of interest. No declarations were made.

2012/20 Minutes and decision summary from the meeting held on Tuesday 10th January 2012.

These were accepted as a true record.

2012/21 Matters arising

2012/16. At the January meeting of the APC DC agreed to write to paediatric leads across the health economy for nominations of individuals who could commit to attendance at these meetings. Clarification was now requested on who the appropriate individuals for NUTH and NTW would be. Contact details were provided and DC will now progress this request.

2012/ 04 Dabigatran

NHS Salford has now submitted their appeal against the NICE FAD relating to dabigatran. There are indications that this appeal will be unsuccessful and that publication of the final NICE guidance is imminent.
An interim document has been produced by the RDTC to assist prescribers in deciding whether dabigatran is an appropriate choice for individual patients. It was acknowledged that this would still be a useful document as it presents a note of caution if the NICE approval is as wide as is expected. There are ongoing concerns around widespread use of dabigatran before more experience is gained with it, especially in the frail elderly, and any information that will assist clinicians in their discussions with patients is to be welcomed.
Clarification was sought regarding the role in cardioversion. The committee was informed that this was NETAG advice.

Decision: The document was approved subject to confirmation with NETAG that their endorsement of use in cardioversion was made following appropriate consideration of efficacy and safety. Dabigatran is not licensed for use in such circumstances.

The minutes of the meeting held in January by Jane Skinner highlight the potential

use of dabigatran in patients being anticoagulated solely for the purpose of cardioversion or other AF procedure, rather than for an increased thromboembolic risk. There is also concern about the delay to effective anticoagulation when warfarin is used in patients with TIA and AF. These patients are not admitted. It was recognised that they could be treated with tinzaparin in the community whilst being anticoagulated with warfarin, but there was a suggestion that these patients be considered for dabigatran, without being treated with warfarin first.
It was noted in those minutes that any use outwith the current NETAG /final NICE position would need to be requested through a submission to the formulary subcommittee. The APC welcomed this.
DC asked if the group convened by JS at the request of the APC should continue to meet in order to advise the APC on the role of other new agents such as apixaban and rivaroxaban. It was felt that this local group, which had specialist clinician representation, had been helpful in relation to dabigatran discussions. Rather than being requested to meet on a regular basis it was agreed that this option would be used in the future to give advice if more specialist input was needed to assist with formulary/APC decisions. It was also pointed out that the Cardiac Network has a role to play and they have been asked to consult with APCs prior to publishing advice relating to medicines.

2012/06 Boceprevir - New product request.
At the January meeting of the APC the committee deferred a decision on Boceprevir approval pending clarity on:

- The place in therapy within specific patient subgroups, particularly in relation to alcohol consumption, HIV status and HEP B status
- The severity of disease needed to make treatment cost effective – the submission states disease level 3 or 4 for treatment naïve patients but the SMC model is based on Level 4 only.
- It is unclear whether patients benefit from treatment or not at this advanced stage …Is the liver disease reversible and will viral clearance prevent liver failure and cancer development? I.e. does clearing virus in advanced liver disease improve patient outcomes?
- The relative benefits of Boceprevir compared to Telaprevir

This information has now been provided and will be considered in conjunction with the new product application for Telaprevir under agenda item 2012/22.

2012/22 Report from the Formulary Sub-committee

Minutes and recommendations from the meeting held on Tuesday 28th February 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 points were highlighted:

- **Morphine sulphate pentahydrate – DepoDur®**

Morphine sulphate pentahydrate (DepoDur®) is an opioid analgesic that has been requested by clinicians in County Durham and Darlington for post operative pain relief in elective and emergency colorectal and gynaecological surgery, and orthopaedic surgery.

After discussion the consensus among the Subcommittee members was that due to the inherent risk of delayed respiratory depression with epidural morphine, DepoDur® is a potentially dangerous preparation. To manage this risk close observation in HDU is required, but it was felt that HDU units would be unable to offer this level of monitoring. Furthermore due to prolonged action of DepoDur® it was felt that this monitoring would be required for up to forty-eight hours and this would potentially result in longer hospital stays. The FSC therefore recommends that the request for DepoDur® should not be approved.
The committee acknowledged the complexities of joint arrangements with health economies outside our area but agreed that efficiencies achieved through joint working
Should be encouraged. Notification of decisions made relating to applications by clinicians in other areas would be communicated to relevant parties by their own representatives on the FSC.

Decision: Refused

- **Infliximab**

Infliximab has been requested for use in the treatment of juvenile idiopathic arthritis (JIA), juvenile dermatomyositis and paediatric onset Behcet's disease.
In JIA it will be used in patients who have not responded to etanercept. In patients with juvenile dermatomyositis and paediatric onset Behcet's disease it will be used where there has been intolerance or lack of response to 1st and 2nd line therapies. While there is some evidence to support the use of infliximab for use in JIA, clinical studies to support its efficacy in juvenile dermatomyositis and paediatric onset Behcet`s disease are limited. It was accepted, however, that this is primarily due to the rarity of the conditions.

It was noted that the potential cost of infliximab used for these indications exceeds the threshold at which point new product requests should be considered by NETAG instead of the Formulary Subcommittee. NETAG have been approached following the FSC meeting to clarify if these uses of this product are on the NETAG work plan.
NETAG stated that no such request has been considered by them and that if a formal submission was made they could add it to the August workplan.
The committee decided to endorse the recommendation made by the formulary subcommittee.

Decision: Approved
Infliximab is approved for use in the treatment of the rare conditions JIA, juvenile dermatomyositis and paediatric onset Behcet's disease. In JIA it will be used in patients who have not responded to etanercept. In patients with juvenile dermatomyositis and paediatric onset Behcet's disease it will be used where there has been intolerance or lack of response to 1st and 2nd line therapies.

- **Nebulised Gentamicin**

Nebulised gentamicin injection has been requested for long term therapy in non cystic fibrosis bronchiectasis. It is not licensed for nebulisation but it is considerably cheaper than nebulised colistin, has been demonstrated to reduce exacerbations, and, due to low systemic absorption, is considered a relatively safe treatment.
The FSC recommend that nebulised gentamicin should be approved as a blue drug. An associated information sheet for primary care was circulated.
Some commissioning issues were raised relating to funding streams required

to facilitate the primary care use of this product. It was agreed that the CCG representatives would progress these issues outwith the meeting in discussions between practices and CCGs.
Subject to minor amendment to the information sheet, the recommendation and information sheet were approved.

Decision: Approved
Nebulised Gentamicin will be included in the North of Tyne Formulary for use in the following circumstance:
- Long term therapy in non-cystic fibrosis bronchiectasis usually in patients having > 3 exacerbations per year with an organism identified as being sensitive to gentamicin
This is an unlicensed indication.
Treatment must be initiated by specialists in Secondary Care only. Patients remain under supervision by secondary care until stable or drug is withdrawn.

- **Buccal midazolam**

A licensed buccal preparation of midazolam (Buccolam®) is now available. In NoT the majority of the Trusts, however, use Epistatus® which is unlicensed. Due to differences in strength and presentation between the two preparations, it is felt that changing to Buccolam® would require significant levels of patient training to undertaken. Epistatus® is in the process of being licensed but it is not clear when this will be competed.
The formulary subcommittee has recommended that the unlicensed Epistatus® preparation should continue to be used and this will be reviewed in 1 year's time.
Concern was expressed over this decision, particularly with regards to use of an unlicensed product when a licensed alternative is now available. It was felt that some of the concerns relating to changeover may have been exaggerated and that we should be supporting a company that has sought to obtain an appropriate license in this patient group.
Following debate, the committee endorsed the decision to retain Epistatus® as the formulary choice but to review this decision in 6 months if no license for this product had been obtained.

Decision: Approved
Epistatus® should continue to be used first line but this decision will be reviewed in 6 months time if it is still unlicensed.

- **Methylthioninium chloride injection (Methylene Blue)**

A licensed formulation of Methylthioninium chloride injection is now available but it is 0.5% injection compared to the existing, unlicensed, preparation which is 1%. The FSC has recommended that Methylthioninium chloride 0.5% injection should be approved for use in theatres and in the poisons unit.
A question was now raised regarding the use in other settings such as endoscopy clinics. It was agreed to remove the restriction to theatres and poisons units.

Decision: Approved
Methylthioninium chloride 0.5% injection is approved for use in appropriate clinical settings.

- **Telaprevir - New product request.**

Telaprevir is a protease inhibitor that has been requested for use in treatment naïve patients with advanced fibrosis, and in treatment experienced patients with evidence of interferon responsiveness who have complied with previous treatment and:

- Relapsed (HCV RNA negative on treatment but relapsed after treatment finished)
- Had partial response (HCV RNA reduced by > 2 logs IU/ML at week 12 but were still HCV RNA positive at week 24).

There is clear evidence of efficacy in combination with Peginterferon plus ribavirin but the cost of treatment is considerable.

The formulary subcommittee had requested further clarification on:

- The proposed place in therapy of telaprevir compared to boceprevir.
- The relative costs of using boceprevir and telaprevir in above patient groups.
- Why is boceprevir being requested for those patients in whom previous response to peginterferon plus ribavirin therapy is unknown?

This clarification has now been received and the APC was asked to consider this along with the additional information requested in January relating to boceprevir use.
It was noted that the SMC has approved both products for all licensed indications and that the NICE FAD for boceprevir is for use wider than is being requested currently in the North of Tyne Area.

Decision

Telaprevir is approved for use in the treatment of :

- Treatment naïve patients with advanced fibrosis (stage 3-4 fibrosis or Fibroscan >11 KPa)
- Treatment experienced patients with evidence of interferon responsiveness who have compiled with previous treatment and relapsed or have had partial response.

Boceprevir use is approved for use in the treatment of :

- Patients who have failed treatment and prior response is not known (usually treated prior to 2007).
  The lead in phase (4 weeks treatment with PEG-IFN and Ribavirin only) with a Boceprevir based regimen allows us to determine whether patients are responsive to interferon or not.

The North of Tyne PCTs will fund treatments in line with the above approvals from 1st April 2012.
Both decisions will be reviewed on publication of the relevant NICE Guidance.

The committee was asked if there was any statement relating to the timeframes within which the formulary subcommittee would not consider products that NICE were due to consider.
It was confirmed that there is currently no such exclusion within the Terms of Reference.

Formulary version 3.5 (January 2012)

This version of the Formulary is now available on the APC website.

2012/23 Report from the Shared Care Group (SCG).
No report received. The group is scheduled to meet later this month.

2012/24 Report from the Anti-microbial Chemotherapy subcommittee.
ML informed the committee that work has begun on updating the Primary Care Antibiotic guidelines. It was noted that the group still need to appoint a new chairperson.

2012/25 Quality, Improvement, Productivity and Performance (QIPP)

- Minutes were received from the meeting held on 22nd February 2012.

RE drew the committees attention to the following points:

- An update on the SHA wide "Waste Campaign". The NE Behavioural Change project will build upon work already started where the NE is leading the way on Medicines Optimisation strategy. There is a project stakeholder event to take place Wednesday 28th March 2012 – 8:30am – 12pm Ramside Hall Durham.
- A draft code of practice for pharmaceutical company representatives and staff with whom they interact for consideration at CCG / practice level has been developed. This was tabled for comment and APC endorsement. It was noted that this was intended to be a document that CCGs may choose to utilise but it would not be a requirement for them to follow as they would be responsible for their own policies. It was agreed that DC would take chairs action to approve this document in 2 weeks time, pending comments.

Decision:
Members to send comments to RE/DC and chairs action to be taken to approve this document.

- Guidance on Prescribing Gluten Free Products.
  A document aimed at supporting clinicians with respect to prescription of gluten free products has been produced following work undertaken across the area and in consultation with various groups. The APC endorsed the use of this document.

DC asked that QIPP minutes are shared with the Formulary subcommittee.

2012/26 HiB vaccine
In September 2011(2011/61) the committee was asked to endorse the use of HiB vaccination as part of the diagnostic process for patients with bronchiectasis. It was explained that as part of the BTS guidelines for patients with bronchiectasis it was recommended that patients have a HiB titre performed and anyone with a low titre is given a HiB vaccine and a retitre performed 6 weeks later. This was part of a diagnostic test which may require the patient to come under the care of an immunologist. Normally the consultant would ask the GP to prescribe and administer the vaccine but concerns had been expressed by a practice who felt that this was not an appropriate request for primary care. Advice was sought at that time from public health and the Health Protection Agency who did not feel that this was recommended by the JCVI and was therefore not appropriate for primary care.
The committee therefore felt at that time that if this was to be part of a diagnostic test then it should be given in the outpatient clinic but noted that there may be cost

implications for referral and inconvenience for the patient.
Since then additional information has been received and a paper was circulated prior to the meeting asking the committee to reconsider the request to use vaccinations as a diagnostic test in non-CF bronchiectasis patients.
It was reiterated that the British Thoracic Society Guidelines recommend that patients with non-CF bronchiectasis are investigated for an underlying immune deficiency.
Patients have bloods taken in the Respiratory clinic to measure baseline levels of specific antibodies against the capsular polysaccharides of both Streptococcus pneumoniae and Haemophilus influenzae type b (or suitable alternatives) and tetanus toxoid.
Where these baseline screenings are low, patients should be immunised with the appropriate vaccine and bloods taken at least 4 weeks later to check individual antibody response.
If levels are still low, this may indicate an immune deficiency, which requires the patient to come under the shared care of an immunologist, and will help determine ongoing treatment options.
Single HiB vaccine is no longer available, so Menitorix® is commonly used (combined HiB and meningococcal C) as is Pneumococcal - Pneumovax®, or Tetanus.

Decision:
The indications for these vaccinations should be extended to include immune testing in non-CF bronchiectasis patients.

It was recognised that there would need to be local protocols around such use, and which vaccine is most appropriate, as well as discussions around the most appropriate setting for such vaccinations but it was agreed that the use of these vaccines in such circumstances was appropriate.

2012/27 Diamorphine to Morphine

A document relating to the above switch was received for information.
Work is ongoing to ensure this changeover is managed in a safe and efficient manner.

2012/28 Documents previously circulated by email

- **NETAG Decision summary** : Ozurdex® dexamethasone ocular implant for uveitis

The above document was noted and endorsed by the APC.

- **Letter re Tapentadol decision**

A letter relating to the decision to reject the application for tapentadol to be included in the North of Tyne formulary was discussed. The committee stands by the previous decision but has agreed an extension to the appeals process until 4 weeks from notification of this decision.

2012/29 APC Guidelines and Statements for review

The information sheet for Dekristol has been updated to reflect recent MHRA advice.

2012/30 Chair's action

DC endorsed the decision to support branded prescribing of salmeterol inhalers following recent warnings.

2012/16 Any other business

- RE asked the committee if a joint Medicines Optimisation Strategy is

something that the APC should take responsibility for. It was agreed that individual organisations are currently responsible for their own Medicines Optimisation strategies but that this is something which could be considered by the APC if CCGs felt it would be useful. It was recognised that this may be a strand of work that would be valuable to CCGs and consideration would be given to including this within the Terms of Reference of the committee.

- RE also asked the committee if the work identified in the Homecare Review is something the APC should take responsibility for. Again it was agreed that this may be a strand of work that may be valuable to CCGs and consideration would be given to including this within the Terms of Reference of the committee.
- ML informed the committee that he had received an application for the inclusion of Nicorette Quickmist in the North of Tyne formulary. A similar application was considered and rejected in June 2011 and there has been no additional information relating to cost-effectiveness submitted. It was agreed that in the absence of new information, products should not be reconsidered within 12 months of application. The applicant will be informed of this decision.

2012/17 Date and time of next meeting

Date and time of next meeting:
Tuesday 8th May
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: 8/5/12**
(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 13th March 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

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
Boceprevir (Victrelis®)	✓ R			Boceprevir is a protease inhibitor that has been requested for the treatment of chronic genotype 1 hepatitis C. Like other protease inhibitors, boceprevir must be given in combination with peginterferon–ribavirin to minimise the emergence of resistance. In January 2012 the committee deferred a decision on Boceprevir approval pending clarity on: • The place in therapy within specific patient subgroups, particularly in relation to alcohol consumption, HIV status and HEP B status • The severity of disease needed to make treatment cost effective • The relative benefits of Boceprevir compared to Telaprevir This has now been received. **Decision: Approved** Boceprevir use is approved in the following circumstances: • Patients who have failed treatment and prior response is not known (usually treated prior to 2007). The lead in phase (4 weeks treatment with PEG-IFN and Ribavirin only) with a Boceprevir based regimen allows us to determine whether patients are responsive to interferon or not. This approval will be reviewed following publication of Nice guidance.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
2) New Requests				
Sodium stibogluconate (Pentostam®)	✓ R			Sodium stibogluconate (SSG) has been requested for the treatment of cutaneous and visceral leishmaniasis. The WHO recommends treating leishmaniasis with sodium stibogluconate or meglumine antimonite at 20mg/kg/day for 20-28 days. Meglumine antimonite is an imported, unlicensed product that is considerably more expensive than SSG. Experience has been gained with SSG in this indication at NUTH, via the IFR route. **Decision: Approved**
Morphine sulphate pentahydrate (DepoDur®)		✓		DepoDur is the only opioid licensed for epidural use. It uses the liposomal delivery system to release morphine sulphate in a controlled manner, reducing peak morphine plasma concentrations and allowing an extended release for up to 48 hours. The efficacy of DepoDur has been established after hip arthroplasty, lower abdominal surgery involving an incision below the umbilicus, and elective caesarean section delivery. Studies have demonstrated that it reduces the amount of postoperative analgesia required, and length of stay. However respiratory depression has also been reported in the studies. **Decision: Refused** The request for DepoDur was not approved. It was felt that the epidural route for morphine following such surgery increases risk as there is as there is an inherent risk of delayed respiratory depression. Close observation, for up to 48hrs, in HDU would therefore be required. This could delay patient discharge.
InteguSeal® IS 100u	✓ R			InteguSeal is a butyl cyanoacrylate 'super glue' based microbial sealant that has been requested for preoperative preparation of the saphenous vein harvest site. Studies have shown that in addition to standard preoperative skin preparation, the application of InteguSeal prior to incision reduces the incidence of surgical site infection. It is therefore anticipated that InteguSeal use will lead to a reduction in infections and may reduce the length of hospital stay. **Decision : Approved** The request was approved. The unit is requested to audit its infections rates.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Aminocaproic acid[u]	✓ R			Aminocaproic acid has been requested for use in paediatric patients undergoing extracorporeal membrane oxygenation (ECMO). ECMO is a technique used for treating acute lung failure. In order to perform ECMO the patient must be systemically anticoagulated. It is also known that there is up-regulation of the fibrinolytic system during ECMO that has the effect of lysing clots that have formed and as a result haemorrhage is the principle complication. Anti-fibrinolytic medicines are useful to prevent delayed bleeding that would otherwise occur. There are three anti-fibrinolytic agents available for use: tranexamic acid, aprotonin and aminocaproic acid. Due to the very specialised nature of ECMO there have been no robust RCTs examining the use of fibrinolytic inhibitors in this population. Aminocaproic acid is the most widely used and studied agent for this indication and the limited evidence available indicates that it reduces the requirements for blood transfusion during ECMO. **Decision: Approved** The committee agreed that on balance the benefits of aminocaproic acid in this indication outweigh the risk.
Telaprevir (Incivo®)	✓ R			Telaprevir is a protease inhibitor that has been requested for the treatment of the following patients: - treatment naïve patients with advanced fibrosis (stage 3-4 fibrosis or Fibroscan >11 KPa) - treatment experienced patients with evidence of interferon responsiveness who have compiled with previous treatment and relapsed or have had partial response. **Decision: Approved** This decision will be reviewed following publication of the NICE Guidance.
3) New formulations & extensions to use				
Infliximab – JIA (Remicade®)	✓ R			Infliximab has been requested for use in the treatment of the rare conditions JIA, juvenile dermatomyositis and paediatric onset Behcet's disease. In JIA it will be used in patients who have not responded to etanercept. In patients with juvenile dermatomyositis and paediatric onset Behcet's disease it will be used where there has been intolerance or lack of response to 1st and 2nd line therapies. While there is some evidence to support the use of infliximab for use in JIA ,clinical studies to support its efficacy in juvenile dermatomyositis and paediatric onset Behcet`s disease are limited but it was accepted that this is primarily due to the rarity of the conditions. **Decision: Approved**

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Tadalafil – PAH (Adcirca®)	✓ R			Tadalafil has been requested for the treatment of pulmonary arterial hypertension (PAH). This is a rare disease characterised by extreme elevations in pulmonary artery pressure, and pulmonary vascular resistance. Mean survival in untreated patients is about 2 years. Sildenafil is currently included in the Formulary for the treatment of PAH. Tadalafil is now also licensed for this indication but, unlike sildenafil, it is only licensed in adults. Studies have evaluated the efficacy when switching from sildenafil to tadalafil. Compared to sildenafil it has the advantage that it is administered once daily and it is thought to be associated with fewer nasal side effects therefore aiding compliance. Experience with tadalafil has been gained at NUTH from clinical trials. **Decision: Approved** The use of tadalafil for the treatment of pulmonary arterial hypertension (PAH) is approved for use in adults for whom treatment with sildenafil is not tolerated or effective.
Nevirapine MR (Viramune®) prolonged - release)		✓		Nevirapine is a potent NNRTI. Nevirapine IR is included in the Formulary. Nevirapine XR has been requested because it is a once daily drug and may improve patient compliance in patients with a high pill burden. Studies have demonstrated that it is as effective and as safe as nevirapine IR. The patent of nevirapine IR is due to expire in December 2012. Both formulations are currently the same price. **Decision: Refused** The committee was not convinced that the XR formulation offers any benefits over the IR formulation and was mindful of the forthcoming patent expiry.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Nebulised Gentamicin[u]	✓ B			Nebulised gentamicin has been requested for use in non cystic fibrosis bronchiectasis. Long term antibiotics are used with the aim of improving symptoms, reducing exacerbation frequency and improving health status. Latest BTS guidelines (2010) recommend inhaled antibiotics in the following circumstances: - Patients having >3 exacerbations per year requiring antibiotic therapy or patients with fewer exacerbations that are causing significant morbidity should be considered for long term nebulised antibiotics. - In such patients, long term nebulised antibiotics should be considered if chronically colonised with *P aeruginosa*. There is evidence to support its use in this indication including a reduction in exacerbations. It is cheaper than nebulised colistin and has a broader spectrum than colistin. **Decision: Approved** Nebulised Gentamicin will be included in the North of Tyne Formulary for use in the following circumstance: - Long term therapy in non-cystic fibrosis bronchiectasis usually in patients having > 3 exacerbations per year with an organism identified as being sensitive to gentamicin This is an unlicensed indication. Treatment must be initiated by specialists in Secondary Care only. Patients remain under supervision by secondary care until stable or drug is withdrawn.
Levobupivicaine 0.625mg/ml & 1.25mg/ml infusion bags	✓ R			The use of levobupivicaine infusion bags for local infiltration in hip and knee replacement surgery has been requested on the grounds that this can produce good results including quicker mobilisation of patients and reduced mortality. The infusion bags are not licensed for local infiltration, although the injections are. In line with NPSA guidelines,however, it is considered safer to use the pre diluted bags than to carry out the manipulations required to dilute the ampoules. There is support from clinicians across both NoT foundation trusts in using the bags. **Decision: Approved** The request should be approved. It should be noted however that concerns were raised regarding the risk of these bags being inadvertently given by the IV route. Individual Trusts should carry out a risk assessment and ensure local safeguards are in place prior to introduction.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Colecalciferol 800iu capsules (Fultium®)	✓			Colecalciferol 800iu (20mcg) capsules have been requested for first line use in long term maintenance treatment of patients with documented vitamin D deficiency following high strength therapy on the grounds that it is a licensed product and that, as a daily preparation, it will improve patient compliance. It has also been requested for use in patients with symptoms and insufficient levels. It is the only licensed vitamin D product currently available. **Decision: Approved**
HiB, Pneumococcal and tetanus vaccines	✓			The British Thoracic Society Guidelines recommend that patients with non-CF bronchiectasis are investigated for an underlying immune deficiency. Testing may be universal, i.e. applied to all cases of bronchiectasis (also advocated by the regional Immunology team) or targeted (directed only at high risk cases). HiB, Pneumococcal or tetanus vaccines are all suitable. As single component HiB vaccines are not available a combination product would need to be used. **Decision: Approved** These vaccinations will be added to the North of Tyne Formulary for immune testing.
4) Products considered by NECDAG				
None				
5) Products considered by NETAG				
Ozurdex® dexamethasone ocular implant for uveitis			✓	**The NHS North East Treatment Advisory Group opted to defer its recommendation regarding Ozurdex® (dexamethasone intravitreal implant) for uveitis pending receipt of a suitable treatment protocol for use within NHS North East.** The group was minded to recommend the use of Ozurdex® for uveitis providing that it is appropriately positioned in treatment pathways.
6) Appeals against earlier decisions by the APC				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Sitagliptin		✓		Sitagliptin was approved for use in November 2008. Following an application for saxagliptin to be added to the formulary (May 2011) the APC endorsed the decision that Saxagliptin would be the DPPIV treatment to used for new patients. Sitagliptin was to be kept for existing patients only with a view to subsequently removing this product from the Formulary. The decision to remove sitagliptin has now been appealed. **Decision: refused** The committee did not feel any new evidence demonstrating the need for two DPPIV inhibitors was presented.
7) Miscellaneous decisions by the APC				
Methylthioninium chloride 0.5%	See Notes			A licensed formulation of methylthioninium chloride injection is now available but it is 0.5% compared to the existing formulation which is 1%. **Decision :** Methylthioninium chloride 0.5% injection is approved for use.
Losartan suspension	See Notes			A licensed losartan suspension is now available and has been requested for use in paediatrics. An unlicensed preparation is currently used because the tablets, when crushed, do not disperse easily in water and this may lead to inaccurate dosing. Usage is anticipated to be low. **Decision:** The licensed product is approved for use as an alternative to crushing tablets for paediatric and adult patients.
Buccal midazolam	See Notes			A licensed preparation of midazolam (Buccolam®) is now available. In the NoT area the majority of Trusts currently use Epistatus®, which is unlicensed. Due to differences in strength and presentation between the two preparations, concern has been expressed that changing to Buccolam® would require significant levels of patient training and may therefore add unacceptable risk. Continuing to use an unlicensed preparation when a licensed one is now available is, however, not a decision that the APC would normally endorse. It is believed that a license application is pending for the current unlicensed product. **Decision:** Epistatus® should continue to be used first line but this decision will be reviewed in 6 months time if it is still unlicensed.
Gliclazide 40mg tablets, Olanzapine 15mg tablets, Levetiracetam 750mg tablets	See Notes			**Decision:** olanzapine 15mg tablets, levetiracetam 750mg tablets and gliclazide 40mg tablets should be included in the Formulary.