North of Tyne
Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 10th January 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
Sue Gordon (SG)	Executive Director of Public Health	NHS NoT
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
Alexander Dyker	Consultant Physician	NUTH
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
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

Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Janet Kelly (JK)	Nurse Clinical Manager	NNTCH

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

2012/01 The resignation of Tom McCullough was noted.
The LPC will nominate a replacement member to represent community pharmacy.

2012/02 MG indicated that he had a current conflict of interest to declare in respect of ownership of MSD shares.
Conflicts of interest would be added to future agendas as a standing item.

2012/03 Minutes of the meeting held on Tuesday 8th November 2011

These were accepted as a true record.

2012/04 Matters arising

2011/ 55 Dabigatran

NHS Salford has appealed the NICE FAD relating to dabigatran on the basis of a failure to differentiate between different patients and the benefit in each of these groups. There will therefore be a delay in the final NICE guidance being published. The decisions taken by the APC on 8th November therefore need reviewed.
The Formulary subcommittee has recommended that we adopt the existing NETAG decision ahead of final NICE Guidance. The potential outcome of the appeal along with the availability of rivaroxaban for the same indication complicates our local decision but in order to ensure consistency across the North East a decision was taken to approve the use of dabigatran in line with NETAG recommendations. This decision will be amended in line with NICE guidance once it is published.
The RDTC have drafted a document in line with previous discussions to assist prescribers in deciding whether dabigatran is an appropriate choice for individual patients. The decision to approve in line with NETAG's position will be incorporated into this guidance and circulated to prescribers.
It was noted that Jane Skinner is leading a local group to discuss dabigatran use in the North of Tyne area and the APC continues to endorse this approach.

Decision: Dabigatran will be added to the formulary as a green drug in line with NETAG recommendations.

2011/ 55 Tapentadol

The secretary has been contacted for clarification of the decision to refuse the application for tapentadol (2011/65) particularly in relation to the statements around cost implications and potential for overuse.
The notes from the original meeting were checked and clarified. The following points were noted:

- It was acknowledged that there is a demonstrated benefit in terms of improved GI tolerability with tapentadol.
- It was noted however that there was no liquid or i/v formulation available and therefore it could not be recommended as a direct replacement for any existing formulary product.
- Although currently slightly cheaper than oxycodone the patent on the latter product is nearing expiry and costs will then be anticipated to fall
- Concern was expressed over managing patient numbers. It was noted that the original application restricted the prescribing of tapentadol but the APC has to consider the potential cost impact across the health economy and prescribing by specialist pain clinicians inevitably leads to increased prescribing in primary care as well.
- There is ongoing work with palliative care colleagues in relation to opioid prescribing and they have not indicated support for this product.

Decision: The original decision relating to tapentadol stands. The secretary will outline the points noted above to the applicant.

The process for notifying applicants of decisions was clarified. Informal feedback following the Formulary subcommittee meetings will be provided by the FSC secretary. This will allow for any additional information/clarification to be provided in a timely manner therefore avoiding any unnecessary delay in a decision being made by the APC. Formal notification of the APC decision will be made by the APC secretary following the APC meeting.

2011/74 Dressings Formulary

The committee was asked to endorse the decisions taken by the review group who met to review Chapter 18 of the formulary to ensure consistency across the North of Tyne area following the move of community services to the acute trusts. The advice of tissue viability nurses, care of the elderly experts and supplies department have all been sought prior to this rationalization.
22 products have been recommended for removal from the formulary, 10 products have been incorporated from existing community formularies and one new product has been recommended.
These decisions were all ratified by the APC and the formulary will be updated to reflect these changes.

2012/05 Appeals against previous decisions

There were no appeals to be heard.

2012/06 Report from the Formulary Sub-committee

a) Minutes and recommendations from the meeting held on Thursday 15th December 2011

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**.
However the following specific points were highlighted:

- **Boceprevir - New product request.**

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. The formulary subcommittee recommended approval of Boceprevir from a clinical perspective assuming clarification that sustained virologic response, as defined in the studies, translates into patient outcomes. They were satisfied about cost effectiveness in view of the recent SMC decisions.

During discussion it was noted:

With regards to Sustained Virologic response (SVR), which is no detectable virus 6 months after stopping therapy, it was noted that NICE consider this as clinical cure.
Boceprevir offers significantly better SVR rates than previous therapies.
The SMC economic evaluation suggests a cost/QALY of approx £12,000 but this depends on which part of the submission is looked at. None of the patients in the paper submitted had concurrent HIV or HEP B infection and they had no evidence of drug or alcohol use in the previous 2 years. It is unclear as to whether this will be true of the patients outlined in the North of Tyne application and therefore whether the same outcomes can be translated to these patients.

Patients who continue to consume alcohol are excluded from dual therapy - clarification is sought that this is the intended case with triple therapy.
The sub-analyses of the trials indicate that more severe cases are more cost effective.
There are different estimates of cost effectiveness between naïve and previously treated patients, and when the SMC applied NICE models on utility & transition, they changed again. The split in cost–effectiveness was on disease scores F0-F3 v F4 – the application is for patients @3-4 not just 4 therefore clarity is needed as to why they would include both at this stage given the relative cost/QALY scores?
NICE is due to publish in May 2012
Telaprevir is another recently licensed treatment option for this cohort of patients. The NICE single technology process does not allow for a direct comparison between the 2 agents but the relative benefits of each therapy would wish to be considered by the APC. The question was raised that Telaprevir may be slightly more effective and this needs clarified.
There are significant cost implications associated with the use of Boceprevir therefore clarity around the cost effectiveness in particular patient cohorts is requested as the trials seem to show a marked difference in effectiveness between patient groups.
The relative benefits in different patient cohorts may be similar but it is the absolute benefit that influences the QALY model and therefore recommendations may reasonably be expected to be different in different patient groups

Decision

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

- **Intranasal diamorphine - New product request.**

This opioid analgesic has been requested for intranasal use in children for the relief of acute moderate-severe pain due to clinically suspected limb fractures, burns and significant fingertip injuries. This use is recommended in College of Emergency Medicine guidelines.

The formulary subcommittee had expressed concerns that use of nasal diamorphine appeared to be adding an unnecessary level of complexity to current procedures, given that these patients would likely require

cannulation at some stage of the acute admission. It was also noted that due to the lack of cannula there would be no easy means of reversal in the event of overdose. Furthermore given the very small volumes of sterile water required to be added to the diamorphine vial the committee felt the risk of dosing errors was significant.
The initial recommendation was to reject the application pending further clarity from the applicant.
This has now been presented to the APC and the following points were discussed:

- With regards to cannulation some patients with burns and long bone fractures are cannulated in the acute situation only for pain relief; once the burn is dressed or the fracture is immobilised, the painful stimulus is much better and they manage on oral analgesia. They may require intravenous access if they require theatre, but this may be hours later.
- Small children can be very difficult to cannulate:
    - there may be significant time delay, and therefore time in pain, between presentation and cannulation – this time can be bridged very well with intranasal diamorphine
    - using intranasal diamorphine to control acute pain leads to much better conditions for cannulation, with a more settled child and therefore fewer attempts required for cannulation leading to a much less unpleasant experience for the child
- with regards to lack of cannula "meaning there is no easy means of reversal of overdose" intranasal diamorphine is used in over 60% of UK paediatric emergency departments. Naloxone can be given intramuscularly if necessary, or rapid intraosseous access is now facilitated by the presence of EZ-IO drills in the emergency department.
- Regarding dilution of diamorphine vials using very small volumes of sterile water leading to an increased risk of dosing errors it was noted that Wockhardt are in the end stages of a licensing application for a proprietary intranasal diamorphine device, the use of which would eliminate the concerns regarding dosing errors, though not those related to concern regarding a need for reversal. This device is available from Wockhardt at present as an unlicensed product.

Decision

The use of intranasal diamorphine should be approved for use in children for the relief of acute moderate-severe pain due to clinically suspected limb fractures, burns and significant fingertip injuries.
The intranasal spray is the preferred formulation for use. The use of this unlicensed product is approved subject to the appropriate risk assessments being carried out by organisations that intend to use it.

b) Formulary version 3.4 (November 2011)
This version of the Formulary is now available on the APC website.

2012/07 Report from the Shared Care Group (SCG)

a) Minutes from December 14th meeting.

HW drew the committee's attention to P3 of the minutes and the problems that can arise when patients who use compliance aids are receiving prescriptions from the GP, but their dementia medication from NTW. Some community pharmacists have performed secondary dispensing of the dementia medication into the patient's compliance aid but this practice is not recommended by the General Pharmaceutical Council or the PCT. Alternatively, some patients are given two compliance aids which can cause confusion. It was agreed that the guideline would be amended to include a paragraph stating that, in some cases, it may be more appropriate for the GP to prescribe on the advice of the specialist during the initiation and titration phase in order to facilitate dispensing into one compliance aid along with any other medications the patient is receiving.
The APC endorsed this recommendation.

b) Shared Care Guidelines

There were no new shared care guidelines for approval.

c) Information leaflets for primary care

- **Retigabine**

The information sheet relating to the use of this product in adults in primary care was approved and will be added to the APC website.

RE informed the committee that Jill McGrath from NHS North of Tyne will attend the shared care group in future to try and facilitate resolution of any commissioning issues regarding shared care guidelines. DC welcomed this progress.

2012/08 COPD treatment review

In July 2011, after the unsuccessful appeal to have indacaterol added to the North of Tyne (NoT) Area Prescribing Committee (APC) Formulary, the committee requested that a review of the current treatments for COPD was undertaken.
ML presented this review which made the following recommendations

- The current list of inhalers/devices on the formulary should be maintained. This will be reviewed as and when newer agents/devices are added to the formulary.
- GP practices should review the use of Seretide MDIs in existing patients with COPD and either ensure that spacer devices are used or switch patients to the Accuhaler device.
- Further detailed audit of prescribing should be undertaken at practice level and using data from secondary care as above (if available). It is suggested that this is undertaken in April 2012.
- Consideration should be given to examining, prospectively, whether the increase of high strength ICS+LABA inhalers, in NoT, has led to improved outcomes, specifically in reduced admissions for COPD exacerbations.

In relation to the second point RE informed the committee that this work has been ongoing in primary care for some time with significant progress having been made.

2012/13 NECDAG Decisions

The following decision summaries were circulated prior to the meeting

- NECDAG Decision summary - Lenalidomide (Revlimid) for Myelodysplastic syndrome with the 5q minus cytogenetic abnormality
- NECDAG Decision summary - Degarelix (Firmagon) for first line treatment of advanced hormone-dependent prostate cancer at with a PSA > 20ng/l at presentation.
- NECDAG Decision summary - FOLFIRINOX Management of selected patients with inoperable pancreatic cancer (First line for inoperable pancreatic cancer in patients with performance status 0-1.)
- NECDAG Decision summary- Gemcitabine and Capecitabine for management of advanced pancreatic cancer.
- NECDAG Cancer Drug Fund Decision – Imatinib: Adjuvant treatment of adult patients who are at significant risk of relapse following resection of GIST
- NECDAG Cancer Drug Fund Decision – Abiraterone in combination with prednisolone for the treatment of metastatic castration resistant prostate cancer which has progressed on or after a docetaxel-based chemotherapy regimen
- NECDAG Cancer Drug Fund Decision - Ipilimumab 2nd line treatment of Metastatic melanoma
- NECDAG Cancer Drug Fund Decision - Bevacizumab in combination with Capecitabine in metastatic breast cancer.
- NECDAG Gateway Decision – Cisplatin and vinorelbine &RTx
- NECDAG Gateway Decision – CapVin in breast cancer
- NECDAG Gateway Decision – Paclitaxel and carboplatin in ovarian cancer

These decisions will be reflected within the North of Tyne formulary.

2012/14 APC Guidelines and Statements for review

None

2012/15 Chair's action

None taken.

2012/16 Any other business

STh questioned if the APC needed to seek membership from an expert in paediatric medicine. This representation would be best used at the formulary subcommittee. DC agreed to write to paediatric leads across the health economy for nominations of individuals who could commit to attendance at these meetings.

2012/17 Date and time of next meeting

Tuesday 13th March 2012.
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:** 13/3/12

(Chair of the APC)

With regards to point 4, it was noted that a direct correlation between the use of high strength ICS +LABA inhalers and admission rates would be hard to demonstrate due to other contributing factors but the RDTC can provide information on inhaler use as well as admission rates.

ML will share the report with the North of Tyne COPD group.

2012/09 Appliance formulary

NUTH have a continence formulary for urethral catheters, urine drainage systems and related products.

In a similar manner to the recent work undertaken with regards to the dressings formulary, it was accepted that there is some benefit to be gained from undertaking similar work in relation to "plastics" and oral nutritional supplements.

The committee discussed whether this fell under the remit of the APC or whether their focus should be on medications. In secondary care the use of these products was primarily the responsibility of acute trust supplies departments but the trusts now have an additional community role to undertake.

It was agreed that these products are prescribable, can have a significant impact on prescribing budgets in primary care and should fall under the remit of this committee.

It was concluded that the committee would support work to rationalise the use of these products in a similar manner to dressings but that any work would need to be led by primary care, working with the relevant nursing, pharmacy and supplies contacts.

The committee would accept and ratify recommendations from such work and would incorporate these into the North of Tyne formulary.

2012/10 Report from the Antimicrobial Chemotherapy Sub-Group

No meeting of this sub-group had been held.

2012/11 Quality, Improvement, Productivity and Performance (QIPP)

- Minutes were received from the meetings held on 21st September and 14th December 2011.

DC sought clarification of the process relating to recommendations from this group. With regards to recommendations relating to a change in formulary position, these will be taken through the formulary subcommittee for consideration. Minutes are presented to the APC for information.

Recommendations relating to mesalazine products are currently being discussed with gastroenterologists.

2012/12 NETAG Decisions

The following decision summaries were circulated prior to the meeting

- NETAG Decision summary - Amifampridine phosphate (Firdapse®) for the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS)
- NETAG Decision summary - OmniPod® continuous subcutaneous insulin infusion pump system

These decisions were accepted by the committee and will be reflected within the North of Tyne formulary.

North of Tyne
Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 10th January 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			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
None				
2) New Requests				
Boceprevir (Victrelis®)			✓ See Notes	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. 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

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Calcium hydroxylapatite (Radiesse®)	✓ R			Radiesse has been requested for use as a vocal cord medialisation injection. Currently available vocal fold augmentation materials are variable in their duration or require significant preparation efforts. These include autologous fat injection, collagen based products and hyaluronic acid based products. Calcium hydroxyapatite (CaHa) is a major component of both bone and teeth and has been used as a biomedical implant in a variety of applications. It is anticipated that hyaluronic acids will be used in patients who are expected to have a shorter life expectancy, whereas Radiesse would be used in patients who are anticipated to have a longer life expectancy dues to its longer duration of action. Another longer term implant is Bioplastique but this needs to be administered in theatre under GA whereas Radiesse can administered in the outpatient setting. Radiesse has been approved by the FDA for this indication. **Decision:** The request for Radiesse is approved.
Artiss® fibrin sealant	✓			Artiss has been requested for use in plastic surgery to close dead spaces, adhere skin graft, close simple wounds and stabilise bone grafts. Tisseel sets too quickly and therefore doesn't allow the surgeon enough time to position the grafts properly. To achieve a slower setting time the thrombin component requires 'off label' dilution, increasing the risk of error. Artiss contains a lower thrombin concentration, does not require dilution and is licensed for this indication. The consistent concentration of Artiss may lead to lower volumes being required leading to compensatory savings, in an addition to very modest savings in nursing time, needles and saline. **Decision:** The request for Artiss is approved.
High strength fluoride toothpaste (Duraphat®)	✓ See Notes			High fluoride toothpastes have been requested for inclusion in the NoT formulary. There are two strengths of this toothpaste available, 2800ppm and 5000 ppm. Both toothpastes are listed as a treatment option for fluoride supplementation in the DOH guideline for 'Delivering better oral health'. **Decision:** Duraphat 2800ppm and 5000ppm fluoride toothpastes will be included in the North of Tyne Formulary for prescribing by dentists and dental hospital prescribers only. It is therefore classified as a restricted drug only.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
3) New formulations & extensions to use				
Methyphenidate (Narcolepsy)	✓ A			Methylphenidate has been requested for the treatment of narcolepsy in paediatrics. It is included in the NoT Formulary for the treatment of ADHD and giggle incontinence, hence there is already a great deal of experience of its use in paediatrics. Treatment options for narcolepsy in the paediatric population are limited and grossly understudied. Products currently included in the NoT Formulary for narcolepsy are modafanil (only licensed for use in adults) and dexamphetamine (very little experience of its use in paediatrics). There is little evidence to support the use of methylphenidate in this indication but there are no alternatives available. **Decision:** The request for methylphenidate for narcolepsy in paediatric patients is approved, subject to informed consent; the preparation of a shared care protocol; and an agreed period of stabilisation prior to GPs taking over prescribing.
Trospium XL (Regurin XL®)		✓		Trospium XL has been requested for the treatment of overactive bladder (OAB). Drugs currently included in the NoT Formulary are oxybutynin, tolterodine IR/XL, solifenacin succinate, trospium IR and fesoterodine. Trospium is an antimuscarinic agent that differs from oxybutynin in that it is hydrophilic and is therefore much less likely to cross the blood brain barrier, hence it is associated with less CNS side effects. It has been suggested that trospium XL would be used for patients who fail to improve with one or two alternative antimuscarinic agents or in whom there is concern about cognitive impairment. Studies are limited, and there have been no head to head studies conducted to compare trospium with other agents or new treatments. Generic IR trospium is also available. **Decision:** the request for Trospium XL is not approved. The committee was not convinced of the advantages of trospium XL over those products already included for this indication and feels that, due to the patent expiry of tolterodine in 2012, there are significant long term cost implications.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Sulphur hexafluoride (SonoVue®)	✓ R			SonoVue is included in the NoT Formulary for visualising blood vessels in the liver and to differentiate between different types of cancer of the pancreas. It has now been requested for use when echocardiography images are unsatisfactory for answering the clinical question due to poor definition. It is licensed for this indication. The alternative is Myocardial Perfusion study and this is a very expensive process. Studies have shown that the use of SonoVue can sometimes prevent the need for requesting cardiac MRI which is the modality used when echo images are unsatisfactory for assessing LV function accurately. The European Association of Echocardiography recommends SonoVue as a safe and effective contrast agent for use in this indication. **Decision:** The request for SonoVue is approved.
Co-phenylcaine Forte spray (Unlicensed)	✓			A single dose Co-phenylcaine 2.5ml is included in the NoT Formulary. It is used to numb the inside of the nose or throat prior to procedures/ investigations, and can be also used to numb the nose if a foreign body needs to be removed. Co-phenylcaine Forte spray is the only multidose product available, and an application for licensing has been submitted to the MHRA. There are considerable savings to be made by converting to this multidose product. **Decision:** The request for Co-phenylcaine Forte® is approved.
Buccal lorazepam for status epilepticus	✓ R			The paediatric team at NUTH has requested the inclusion of Lorazepam 2mg/ml and 4mg/ml suspension in the NoT Formulary. It would be prescribed in a small number of patients for buccal administration, in patients with status epilepticus in whom buccal Midazolam, rectal paraldehyde and rectal diazepam are ineffective. Both strengths of Lorazepam suspension are unlicensed. The lorazepam injection is not suitable for buccal use at home. **Decision:** The request for lorazepam 2mg/ml and 4mg/ml suspension is approved. It will be classified as a Red drug.
Sitagliptin		✓		Previously, sitagliptin was removed from the NoT Formulary and replaced with saxagliptin. A request has now been received to consider reinstating sitagliptin as a treatment option for new patients on the grounds that: • It is more established and has more safety data • Sitagliptin has a license for monotherapy, dual oral therapy and triple oral therapy; whereas saxagliptin has a license for combination therapy only. It has been suggested that saxagliptin would only be used in those patients with renal insufficiency that require combination therapy. **Decision:** The request for sitagliptin to be reinstated is not approved.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Intranasal diamorphine	✓ R See Notes			Intranasal diamorphine has been requested for use in children for the relief of severe pain due to clinically suspected limb fractures, burns and significant fingertip injuries. This treatment option is recommended in a guideline developed by the College of Emergency medicine. Current options for this group of patients includes PO/IM morphine, however it can take up to 10 minutes to see significant analgesic effect. Intranasal diamorphine may reduce the need for intravenous opiates for simple manipulations in older children. **Decision:** The use of intranasal diamorphine is approved for use in children for the relief of acute moderate-severe pain due to clinically suspected limb fractures, burns and significant fingertip injuries. The intranasal spray is the preferred formulation for use. The use of this unlicensed product is approved subject to the appropriate risk assessments being carried out by organisations that intend to use it.
Buccal prochlorperazine (Buccastem®)	✓			Prochlorperazine 3mg buccal tablets (Buccastem®) have been requested for the treatment of nausea associated with migraine when the oral route cannot be used due to vomiting. Studies have demonstrated that it has a quicker onset of action compared to oral prochlorperazine. It is a recommended treatment option in guidelines produced by the British Association for the Study of headache. This product is frequently used in primary care. **Decision** – The request for Prochlorperazine 3mg buccal tablets is approved.
4) Products considered by NECDAG				
Lenalidomide (Revlimid) for Myelodysplastic syndrome with the 5q minus cytogenetic abnormality		✓		REJECTED from Standard NHS Funding. REJECTED from Cancer Drug Fund CDF.
Degarelix (Firmagon) for first line treatment of advanced hormone-dependent prostate cancer at with a PSA > 20ng/l at presentation.	✓			Approved on the condition that the manufacturer either discounts or rebates the cost of degarelix to be equivalent to the cost of gosarelin.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
FOLFIRINOX Management of selected patients with inoperable pancreatic cancer (First line for inoperable pancreatic cancer in patients with performance status 0-1.)	✓			Approved.
Gemcitabine and Capecitabine for management of advanced pancreatic cancer.		✓		Not Approved.
Imatinib: Adjuvant treatment of adult patients who are at significant risk of relapse following resection of GIST	✓			Approved from NHS Funding
Abiraterone in combination with prednisolone for the treatment of metastatic castration resistant prostate cancer which has progressed on or after a docetaxel-based chemotherapy regimen	✓ See Notes			Approved from cancer drug fund on the condition the manufacturer provides abiraterone with the discount agreed as part of the patient access scheme.
Ipilimumab 2nd line treatment of Metastatic melanoma	✓ See Notes			NECDAG reviewed this indication on 30th November 2011 and concluded that Ipilimumab does not meet the normal NHS Cost Effectiveness Criteria. Rejected from Standard NHS funding Approved from Cancer Drug Fund (subject to ongoing review)
Bevacizumab in combination with Capecitabine in metastatic breast cancer.	✓ See Notes			NECDAG reviewed this indication on 30th November 2011 and concluded that Avastin with Capecitabine does not meet the normal NHS Cost Effectiveness Criteria. Rejected from Standard NHS funding Approved from Cancer Drug Fund (subject to ongoing review)
Cisplatin and vinorelbine &RTx	✓			Approved by NECDAG 30.11.11
CapVin in breast cancer	✓			Approved by NECDAG 30.11.11
Paclitaxel and carboplatin in ovarian cancer	✓			Approved by NECDAG 30.11.11

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
5) Products considered by NETAG				
Amifampridine phosphate (Firdapse®) for the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS)		✓ See Notes		**The NHS North East Treatment Advisory Group does not recommend Firdapse® except where interruption to therapy with amifampridine is considered to present a critical clinical situation.** This recommendation is contingent on a discounted price specified within a patient access scheme and only if the use of amifampridine is a continuation of therapy in accordance with existing commissioning arrangements (NETAG recommendation AFP-LMS-JUL10).
OmniPod® continuous subcutaneous insulin infusion pump system		✓ See Notes		**The NHS North East Treatment Advisory Group does not recommend the OmniPod® insulin infusion system.** The group was concerned that differences relating to clinical and patient orientated outcomes compared with other pump systems had not been adequately demonstrated. Therefore the OmniPod® system does not represent cost-effective use of resources. Patients already using OmniPod® should continue to use the system until such time that they or their clinician consider it appropriate to cease.
6) Appeals against earlier decisions by the APC				
No appeals were heard				
7) Miscellaneous decisions by the APC				
Dabigatran	✓			NHS Salford has appealed the NICE FAD relating to dabigatran on the basis of a failure to differentiate between different patients and the benefit in each of these groups. There will therefore be a delay in the final NICE guidance being published. The decisions taken by the APC on 8th November therefore needed to be reviewed. The committee now approves the use of dabigatran in line with NETAG recommendations. It is suitable for prescribing by primary and secondary care clinicians. This decision will be amended in line with NICE guidance once it is published.
NICE TA237 – Macular oedema (diabetic) Ranibizumab				NICE has rejected Ranibizumab and it will be removed from the North of Tyne Formulary.