North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 8th May 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		
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
Janet Kelly (JK)	Nurse Clinical Manager	NNTCH
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Zahra Irranejad	Head of Prescribing (Provider)	North of Tyne PCTs
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

Mark Burdon	Community Pharmacy Representative	NoT LPC

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

2012/33 Declarations of interest

No declarations were made.

2012/34 Appeals

Tapentadol – The applicant had notified the committee of the intention to appeal but was not present. The original decision was upheld.

Nevirapine – Ian Campbell presented the appeal on behalf of the applicant. The following points were noted:

- Historically nevirapine has been used in patients in whom other regimens would have disadvantages (e.g. women desiring to become pregnant and possibly those with a previous psychiatric history) and only within the CD4 cell count recommendations.
- Nevirapine has a low genetic barrier to resistance and is therefore non-forgiving of poor levels of adherence.
- NICE reviewed several RCTs of interventions to reduce dose frequency and found that adherence may increase with once daily dosing.

The committee considered the above points but was not convinced that the PR formulation offers any benefits over the IR formulation and was mindful of the forthcoming patent expiry.

Decision: Refused

2012/35 Minutes and decision summary from the meeting held on Tuesday 13th March 2012.

These were accepted as a true record.

Matters arising

2012/36 2011/55 and 2012/27. The updated NECN guidelines are now approved and include the new recommendation that morphine is the first line injectible opiate to be used.

2012/37 Report from the Formulary Sub-committee

Minutes and recommendations from the meeting held on Thursday 26th April 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:

- **Indacaterol** – Additional information had been submitted to the committee following the formulary subcommittee meeting on 26/4/12. This was considered. It was noted that that while there is evidence to suggest that indacaterol is more efficacious than twice daily salmeterol and tiotropium in terms of lung function and symptom control, there is currently no evidence that the use of indacaterol results in fewer hospital admissions. Concerns were also expressed that there is an increased risk of upper respiratory tract infections with indacaterol.

  The committee felt that the clinical advantages are limited and that the lack of a combination product is a disadvantage. There is also a concern that indacaterol will be less cost effective than salmeterol now that the patent for salmeterol has expired.

  It was noted that despite the fact that the North of Tyne COPD Guidelines Group endorsed use of this product they had not addressed the

commissioning issues associated with it. It was suggested that groups which had representative commissioning involvement/membership (that dealt with commissioning issues/questions as part of their decision making process) would be more likely to have their recommendations endorsed by the APC when submitted.

Decision: Refused

- **Tobi Podhaler** – it was noted that there has been a price adjustment for this product which now makes it cost-comparable to tobramycin nebules. The committee accepted that there were benefits of TOBI Podhaler with regard to convenience, but there was some concern that this would lead to use beyond the short term use recommended.

Decision: Approved
TOBI Podhaler should be approved for short term use in limited circumstances. It should be used for courses of no longer than two weeks. TOBI Podhaler is not to be used for chronic therapy

- **Mesalazine preparations** – there have been several requests for different branded mesalazine products to be considered for inclusion in the formulary which are equivalent to previously refused products. A comprehensive review of these products was carried out in 2010. It was agreed that unless there was new clinical benefit being demonstrated these applications could be rejected at submission.

- **Dovobet gel** – whilst the committee was minded to accept the application, there was concern over the potential for inappropriate use. The applicant will be 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.

Decision - Deferred

- **Atorvastatin chewable** - There is the potential for considerable savings if atorvastatin chewable is prescribed first line ahead of simvastatin suspension where solid dosage forms cannot be used. It was noted that people should be assessed for the benefits and risks of treatment, including considering any co-morbidities and the preferences of the patient, when deciding about treatment.

Decision – Accepted
Atorvastatin chewable tablets are recommended for first line use ahead of simvastatin suspension where solid dosage forms cannot be used

- **Morphine MR** - there may be considerable savings to be made if there was a review of the oral morphine products currently included in the Formulary. It was agreed that this work should be undertaken by the QIPP Board. Points that need to be considered include current usage and costs, Palliative Care guidelines and acceptance for converting existing patients as

well as potential savings in both primary and secondary care.

- **Fesoterodine** - a request has been made from the Urologists to have to Red status of fesoterodine changed to specialist, on grounds that this was proving difficult for the patients and consultants. The original hospital only status was recommended in order to ensure use was restricted only to 3rd line use as an option in preventing progression on to Botox and then potentially surgery. The committee agreed to consider this request on receipt of audit data demonstrating that it had reduced the progression to Botox/surgery as per the original application.
  It was recommended that a review of products included in this section should be carried out when tolterodine comes off patent.

- **IFR processes** – RE expressed concern that the formulary subcommittee minutes, on 2 occasions, referred to previous use of a product via Individual Funding Requests. Discussion ensued as to IFR processes and when an IFR request should progress to a formulary application. IC confirmed that appropriate governance was in place within NUTH to ensure correct use of IFR processes. All IFR requests from NUTH are approved internally prior to submission to the PCT for approval. SC indicated that she has previously requested that commissioners provide details of all IFR requests from individual trusts in order to ensure appropriate governance around these but had been refused on the grounds of patient confidentiality. RE agreed to raise these issues with Mike Guy.

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

2012/38 Report from the Shared Care Group (SCG).

Minutes from the meeting of 21/3/12 were received.

Dr Wynne highlighted the following points to the committee:

- There remain concerns around the commissioning of shared care guidelines. Jill McGrath has agreed to join the committee but was unable to attend the March meeting. DC informed the committee that he had a meeting arranged with Jackie Cairns from Northumberland to discuss shared care.
- Changes to legislation have occurred which allow controlled drugs to be prescribed by independent prescribers. The committee therefore agreed that changes to the methylphenidate shared care guidelines should be changed to reflect this.
- The shared care guideline for methylphenidate in narcolepsy treatment in children and young people would not be progressed. The specialist involved had confirmed he did not need this developed further.
- A document for GPs to use if intending to withdraw from a shared care agreement had been circulated. NTW had raised concerns including
  - The rationale for the development of the form
  - A standardised form did not replace the need for clinician to clinician discussion
  - A 28 day notification period of the intent to withdraw from shared care may be insufficient to allow for a specialist appointment to be arranged

HW informed the committee that GPs on the shared care group had asked for this form but the committee felt this approach may lead to difficulties for patients and

endorsed the need for clinical discussion before any withdrawal from shared care. HW agreed to feed back to the group.

2012/39 Report from the Anti-microbial Chemotherapy subcommittee.

ML informed the committee that the group has now met to begin work on updating the Primary Care Antibiotic guidelines. Terms of Reference are to be reviewed and minutes plus revised TORs will be forwarded to the APC.

2012/40 Quality, Improvement, Productivity and Performance (QIPP)

Minutes are still to be received from the meeting held on 18/4/12.
These will be circulated to members on receipt.
RE highlighted the following points:

- The proposed QIPP work stream and Incentive scheme targets have been sent to CCG groups for comment.
- A paper around tariff excluded drugs and contracting had been shared with the group and initial agreement had been obtained to open discussions with the trusts regarding audit of tariff excluded drugs.

2012/41 NoT APC Website

The website has been redesigned.
Some links may need updating. SC agreed to circulate these for onward communication.

2012/42 NPC Competency Framework for Local Decision Making

There has been an update to the document published in Feb 2011. RE agreed to form a subgroup of CCG members and APC members to review this.

2012/43 Documents previously circulated by email

- NETAG Treatment appraisal summaries
  - Aflibercept (Eylea®) for age-related macular degeneration
  - Collagenase (Xiapex®) for Dupuytren's contracture – appeal
  - Fampridine (Fampyra®) in multiple sclerosis
  - Ozurdex® dexamethasone ocular implant for uveitis
  - Paliperidone depot injection (Xeplion®) for schizophrenia – appeal
- NECDAG minutes – 21/3/12
- NECDAG CDF decision – Denosumab in selected patients with advanced breast or prostate cancer with bone metastases – 26/3/12
- NECDAG CDF decision – Vemurafenib for 1st line treatment of inoperable or metastatic BRAF V600 mutation +ve melanoma – 26/3/12

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

2012/44 APC Guidelines and Statements for review

None received

2012/45 Chair's action

- **Dabigatran**

  DC informed the committee that he had approved the document on dabigatran that had been produced for the committee by the RDTC. This is available on the website.
  The committee accept that dabigatran may be used in cardioversion if a cardiologist feels that it is the appropriate choice of agent for their patient.
  Concern was expressed that advice on the NETAG website is now at odds

with NICE recommendations.
The secretary agreed to write to NETAG requesting that they ensure their website is updated following publication of NICE Guidance that supersedes any recommendation they previously made.

2012/46 Any other business

- SW informed the committee that NECDAG are to submit a response to the DoH consultation on complicated molecules. APC members will be copied in to this response

2012/47 Date and time of next meeting

Date and time of next meeting:
Tuesday 10th July
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: 10/7/12**
(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 8th May 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				
Indacaterol (Onbrez Breezhaler®)		✓		This long acting beta2 agonist is licensed for once daily administration in COPD. It was proposed that it may be clinically advantageous compared to twice daily preparations as compliance is often poor in patients with COPD. It was noted that that while there is some evidence to suggest that indacaterol is more efficacious than twice daily salmeterol and tiotropium in terms of lung function and symptom control, there is currently no evidence that the use of indacaterol results in fewer hospital admissions. **Decision** – The committee felt that the clinical advantages are limited and that the lack of a combination product is a disadvantage. There is also a concern that indacaterol will be less cost effective than salmeterol now that the patent for salmeterol has expired.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Eviplera® & rilpivirine	✓ R			Eviplera is a once daily, fixed dose, combination product for the treatment of HIV containing emtricitabine + rilpivirine + tenofovir disoproxil. It has been requested for patients who cannot tolerate Atripla (emtricitabine + efavirenz + tenofovir disoproxil). Efavirenz is associated with neuro-psychiatric adverse events and significantly reduces the activity of oral contraceptives. Rilpivirine has been shown to be associated with a lower incidence of adverse events and can be concomitantly used with oral contraceptives. Rilpivirine is requested for patients who, due to renal impairment, may require reduced doses that are not able to be accommodated by the fixed combination product but by using the individual components. **Decision:** Eviplera was approved for use in patients who cannot tolerate Atripla (emtricitabine + efavirenz + tenofovir disoproxil). Rilpivirine was approved for patients who, due to renal impairment, require reduced doses that are not able to be accommodated by the fixed combination product.
Pill Glide		✓		Pill Glide is a flavoured spray classified as a medical device that has been launched to improve the ability for children to swallow tablets/ capsules. It is sprayed into the mouth, the tablet is then placed into the mouth and then the tablet is swallowed with a few sips of water. Clinical data to support its use is very limited. **Decision:** Pill Glide was not approved.
Enalapril- Postnatal hypertension	✓			Enalapril is recommended in CG107- Hypertension in pregnancy guideline. **Decision:** Enalapril will be added to the NoT formulary for use in breastfeeding mothers only. Mothers will be converted to ramipril when no longer breastfeeding.
3) New formulations & extensions to use				
TOBI Podhaler®	✓ R			TOBI Podhaler has been requested for the suppressive therapy of chronic infection with *Pseudomonas aeruginosa* in adults and children aged 6 years and older with CF. Nebulised tobramycin is currently used but this is very time consuming, leading to significant compliance issues. Tobi Podhaler is a portable, breath actuated, dry powder inhaler that is much quicker to use and requires minimal set up and cleaning time. Studies have shown that it is as efficacious as nebulised tobramycin (TOBI). **Decision:** Approved for short term use. It should be used for courses of no longer than two weeks and it is expected that usage is kept to a minimum. TOBI Podhaler is not to be used for chronic therapy instead of nebulised therapy.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Fentanyl citrate (Abstral®)			✓	Abstral is a sublingual fentanyl tablet that has been requested for breakthrough pain relief for patients undergoing radiotherapy, who have difficulty swallowing/cannot swallow and are experiencing grade 3+ mucositis. NETAG has previously considered the use of novel oramucosal and nasal fentanyl for breakthrough pain associated with cancer and these are not recommended for use in NHS North East. **Decision:** The committee was reluctant to approve Abstral for this indication, but agreed that there was a need to seek further information before a final decision could be made. Clarification was needed regarding: • Given that there is no published data in patients with mucositis is the applicant able to provide any other evidence to support its use in this group of patients? • How are these being patients being fed and what methods are currently used to provide background analgesia and breakthrough pain relief?
Mesalazine 800mg MR tablets (Octasa®)		✓		In 2010, the NoT APC conducted a review of the available mesalazine products and it was agreed that Mesren MR was to be used first line in all new patients and Asacol MR should be used for existing patients only. Octasa® has been proven to be bioequivalent to Asacol MR. **Decision:** Octasa should not be approved as it is considerably more expensive than Mesren and the rebate scheme to equalise the price with Mesren in primary care would be difficult to administer.
Intranasal midazolam[u]			✓	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. It is administered using a syringe and atomiser, usually at a stat dose of 10mg midazolam. In 2008, the NPSA released an alert for high strength midazolam injection. Studies have shown, however, that adverse events are rare and easily managed and the timing of onset, treatment and recovery is appropriate for the dental setting. **Decision:** In light of the NPSA alert the committee agreed that further information was required before a final decision could be made. In particular the justification for this particular strength? A risk assessment should be undertaken and the committee informed of the identified actions to minimise the risk from having stocks of the 20mg ampoules in the clinical area.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Anakinra[u] – severe acute gout	✓ R			Anakinra has been requested for the treatment of severe gout in patients who have not responded to other treatment and for patients with pseudogout who have failed to respond to conventional treatment or unable to tolerate conventional treatment. Published data is very limited however patients have been shown to respond to treatment well. **Decision:** The request was approved.
Dovobet® gel			✓	Dovobet gel is a vitamin D analogue/ topical corticosteroid that has been requested for the treatment of scalp and mild to moderate non scalp plaque psoriasis vulgaris in adults. Dovobet ointment is already included in the formulary but is only licensed for the treatment of stable plaque psoriasis. Dovobet gel is less greasy than the ointment and this may aid compliance. In addition it can be used on the scalp. **Decision:** The committee is minded to approve the request but have requested further information as to the intended position in therapy compared with other available products, how use will be kept to within the licensed duration(s) and how often treatment would be expected to be repeated.
AdCal D_3® caplets			✓	**Decision:** The formulary subcommittee have asked for additional information relating to dosing and compliance before a decision can be made.
Gastrografin	✓			**Decision:** Gastrografin should be added to the Formulary.
Meningitis ACWY conjugate vaccine	✓			This vaccine is recommended in the DOH 'green book' for patients < 5 years and asplenic patients. It is stated that it gives a better immune response and more prolonged duration of action in preference to the polysaccharide version. **Decision:** The vaccine will be added to the Formulary as per 'green book' advice.
4) Products considered by NECDAG				
Denosumab in selected patients with advanced breast or prostate cancer with bone metastases	See notes			NECDAG reviewed this indication on 21st March 2012 and concluded that Denosumab does not meet the normal NHS Cost Effectiveness Criteria and therefore rejected from Standard NHS funding. On 26/3/12 it was approved from Cancer Drug Fund (subject to ongoing review) A limited access proposal was accepted to allow the use of Denosumab in selected patients with advanced breast or prostate cancer with bone metastases, who have: • poor venous access and intolerance of oral bisphosphonate • mild/moderate renal impairment and intolerance of oral bisphosphonate • intolerance of intravenous and oral bisphosphonate It was noted that prescribing should be initiated on consultation with an oncologist.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Vemurafenib for 1st line treatment of inoperable or metastatic BRAF V600 mutation +ve melanoma	See notes			NECDAG reviewed this indication on 21st March 2012 and concluded that Vemurafenib does not meet the normal NHS Cost Effectiveness Criteria and therefore rejected use from Standard NHS funding. On 26/3/12 it was approved from Cancer Drug Fund (subject to ongoing review) for 1st line treatment of inoperable or metastatic BRAF V600 mutation +ve melanoma. Note • Patients who received vemurafenib are ineligible to then receive 2nd line Ipilimumab • Mutation +ve patients who are currently receiving 1st line dacarbazine have option to receive vemurafenib as a 2nd line therapy. • Patients diagnosed from 21st March 2012 are not eligible for 2nd line vemurafenib. • Ongoing funding for this and iplilumimab is subject to presentation of audit data to NECDAG with 12 months.
5) Products considered by NETAG				
Aflibercept (Eylea®) for age-related macular degeneration			✓	On 20/3/12 the NHS North East Treatment Advisory Group deferred a decision on the request by the North East Retinal Group to conduct an appraisal of and issue a recommendation for the use of aflibercept (Eylea®) within its anticipated licensed indication for (wet) age-related macular degeneration.
Collagenase(Xiapex®) for Dupuytren's contracture – appeal	✓			On 20/3/12 The North East Treatment Advisory Group upheld an appeal of their previous recommendation on the use of collagenase (Xiapex®) within its licensed indication for the treatment of Dupuytren's contracture as a substitute for established surgical interventions. Collagenase(Xiapex®) is now approved for Dupuytren's contracture limited to one joint or cord and where the flexion contracture is greater than 40º from the horizontal plane. The group recommends that treatment is periodically audited against the recommended treatment criteria to include assessment of baseline and post-treatment flexion contracture angle.
Fampridine (Fampyra®) in multiple sclerosis		✓		The NHS North East Treatment Advisory Group does not recommend the use of fampridine (Fampyra®) in multiple sclerosis.
Ozurdex® dexamethasone ocular implant for uveitis	✓ See notes			On 20/3/12 the NHS North East Treatment Advisory Group conducted an appraisal of, and issued a recommendation for, the use of Ozurdex® within its licensed indication for the treatment of posterior segment uveitis. The Group recommends Ozurdex® (dexamethasone intravitreal implant) for uveitis only in accordance with the defined treatment protocol from the North East Retinal Group.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Paliperidone depot injection (Xeplion®) for schizophrenia – appeal		✓		On 20/3/12 The North East Treatment Advisory Group considered an appeal of their earlier rejection of the use of paliperidone depot injection within its licensed indication for the treatment of schizophrenia and as an alternative to risperidone depot injection. The appeal was rejected. The North East Treatment Advisory Group does not recommend paliperidone depot injection (Xeplion®) for schizophrenia. The group noted uncertainty regarding clinical efficacy and was not satisfied that cost-effectiveness had been adequately demonstrated.
6) Appeals against earlier decisions by the APC				
Nevirapine MR (Viramune®) prolonged - release)		✓		At the meeting of 13/3/12 the application to have Nevirapine MR (Viramune®) prolonged - release) included in the formulary was rejected. Nevirapine is a potent NNRTI that is included in the formulary in the immediate release tablet form. 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. The committee was not convinced that the XR formulation offers any benefits over the IR formulation and was mindful of the forthcoming patent expiry. **Decision:** The original decision was upheld on the basis of future savings when the patent of the immediate release preparation expires.
7) Products considered by NICE				
TA247 – Tocilizumab (rapid review TA198)	✓			The formulary will reflect the recommendations in the NICE TA
TA248 – Diabetes (type 2) exenatide (prolonged release)	✓			The formulary will reflect the recommendations in the NICE TA
8) Miscellaneous decisions by the APC				
Clopidogrel 300mg tablets	See Notes			Since generic clopidogrel is now available, it is considerably cheaper to prescribe 8 x 75mg clopidogrel tablets as opposed to 2 x 300mg tablets, when loading patients prior to intervention. **Decision:** Clopidogrel 300mg tablets should be removed from the Formulary.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Nicorette 15mg inhalator	See Notes			Nicorette 10mg inhalator was included in the NoT Formulary and has now been discontinued. The only alternative product available is the Nicorette 15mg inhalator. **Decision:** Nicorette 15mg inhalators should be added to the formulary. The committee has asked for a full review of the nicotine products that are currently included in the Formulary.
Atorvastatin chewable	✓ See Notes			There is the potential for considerable savings if atorvastatin chewable is prescribed first line ahead of simvastatin suspension where solid dosage forms cannot be used. People should be assessed for the benefits and risks of treatment, including considering any co-morbidities and the preferences of the patient, when deciding about treatment.
Clonidine IV – use in critical care				Clonidine IV is currently included in the Formulary for use 'mainly in paediatric ITU units'. Colleagues have asked for its approved use to be extended to include adult ITU patients for delirium and agitation, often around extubation. **Decision:** The formulary should be amended to reflect this extended use.
Dabigatran – use in cardioversion				The APC accept that the use of dabigatran prior to cardioversion is in line with NICE approval and endorses its use in these circumstances if the patients cardiologist recommends this.