North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 12th November2013 at Northumbria House, Cobalt Business Park, North Tyneside

Present: Dr Simon Thomas chaired the meeting in the absence of Prof David Campbell

Anne-Marie Bailey	Senior Medicines Optimisation Pharmacist	NECS
Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
Ian Campbell (IC)	Assistant Director of Pharmacy	NUTH
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Alexander Dyker	Consultant Physician	NUTH
Janet Kelly	Chief Matron for Community Services	NHCT
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Peter McEvedy (PMcE)	GP and Prescribing Lead	NHS Northumberland CCG
John Ross (JR)	Patient Representative	
Wendy Ross	GP and APC Representative	NHSNewcastle North & East CCG
Helen Seymour	Senior Medicines Optimisation Pharmacist	NECS
Simon Thomas (Chair)	Consultant Clinical Pharmacologist	NUTH
Susan Turner (STu) (Professional Secretary)	Medicines Optimisation Pharmacist	NECS
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Sue Dickinson	Director of Pharmacy	RDTC
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Sue Gordon (SG)	Consultant in Public Health	NHS England
Tamsin Oswald (TO)	Consultant Microbiologist	NHCT

NoT LPC	North of Tyne Local Pharmaceutical Committee
NHSE	NHS England
NHCT	Northumbria Healthcare NHS Foundation Trust
NECS	North of England Commissioning Support Organisation
NTWT	Northumberland Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre

2013/83 Declarations of interest

No relevant declarations made.

2013/84 Appeals

Dymista.
Dr Louise Michaelis attended the meeting to present the grounds of her appeal. The committee had refused the application for Dymista in September due to the lack of strong evidence of additional benefit over currently available therapies which were deemed to be more cost-effective.

Dr Michaelis outlined the following, as the basis of her appeal:

The patients she sees in clinic are refractory patients who have poor or only partial response to current therapy. One third of these patients currently go on for desensitisation but there are cohorts of patients, including those with Cystic Fibrosis who have co-existing asthma and inflammatory disease and those with all 5 atopic diseases, that are often not suitable for immunotherapy.
She also suggested that a proportion of patients currently referred for immunotherapy (costing between £2000 and £6000 depending on treatment length) may avoid the need for this if Dymista was available for use.

She stated that Dymista :

- Has proven superior efficacy over current standard treatments
- Treats Nasal and Ocular symptoms irrespective of disease severity
- Is consistently superior for treating all symptoms of AR
- Does not have the same washout effect that using two products separately would have
- Use would result in 1 in 7 moderate to severe AR patients achieving full symptom relief (nasal and ocular symptoms) in 14 days.

It was also claimed that:

- Concurrent administration of separate, commercially available components will not benefit from the novel formulation and the advanced delivery spray device.
- There will be washout of the insoluble steroid component by the aqueous azelastine spray, a dilution effect of combining separate sprays
- Dosage frequencies are different which will lead to dose confusion-overdosing of FP or under dosing of AZE
- Very high likelihood of poor compliance with two intranasal sprays leading to treatment default or sub-optimal benefit.
- Safety profile of using separate sprays together has not been established.

Dr Michaelis stated that seasonal and perennial rhinitis often goes on to cause asthma and that this is a vast problem for paediatricians. Current research suggests control of allergic rhinitis can lead to a reduced incidence of asthma and that for some of her more severe patients this could mean the difference between being accepted for transplantation or not.
She suggested that Dymista use could initially be positioned for use in children >12 years with stage 3 asthma, and therefore on 4 asthma medications, who are not suitable for immunotherapy. She proposed that work could be undertaken with primary care to redesign the current treatment pathway to allow management of difficult patients in primary care and hence reduce the need for referral into secondary care.

The committee asked for the evidence behind the claim that control of allergic rhinitis could prevent allergic cascade and also were unclear of the evidence behind the assertion that the use of the two components as separate products was less effective than the combined product.

Dr Michaelis left the meeting at this point.
On reflection the committee was not convinced by the benefit of the combination inhaler and indeed felt that there is more chance of controlling side effects by using individual preparations tailored to response. It was also felt that the cohort of patients being discussed (age >12) will often have developed asthma at a much younger age and therefore the proposal that control of allergic rhinitis could prevent this development was not applicable in this cohort. The appeal seemed to be based on a cohort of patients that was not the focus of the original application.

Decision: Appeal rejected.
The original decision stands but the committee would be receptive to a new application for the specific groups of difficult to treat patients outlined in the appeal if there was sufficient evidence provided to demonstrate that seasonal and perennial rhinitis often goes on to cause asthma and that control of this could prevent that progression.

2013/85 Minutes and decision summary from the meeting held on Tuesday 10th September 2013.

These were accepted as a true record with the exception of item 2013/74 which will be amended to reflect the agreed discussions in relation to preservative free eye drops.

2013/86 Matters arising.

2013/87 Action Log

The action log will be updated to reflect the following:

- APC summary information for newer oral anticoagulants – action completed.
- Newer Oral Anticoagulants – work on the local patient decision aid and Anticoagulant card will be put on hold as the committee were informed that this work is being picked up nationally.
- Tapentadol – Agreement was reached in September that a blue information document would be produced and clinic letters adjusted to highlight that this is a secondary care initiated drug only. It has now been agreed that a single information sheet emphasising the formulary position will be produced for attachment to clinic letters. ML to progress.
- Lisdexamfetamine shared care guideline – ML is working with the applicant to ensure completion of this.
- Linaclotide blue information sheet - ML is working with the applicant to ensure completion of this.
- Preservative free eye drops – ML will work with the ophthalmology department to define precise criteria where these are appropriate for use.
- Metoclopramide – information circulated.
- Medical administration Aids Support Tool – ML agreed to circulate this to members.

2013/88 Report from the Formulary Sub-committee

Formulary version 4.6 is now available on the APC website.

Minutes and recommendations from the meeting held on 24th October 2013.

The above minutes and recommendations were received by the committee.
The summary of decisions made by the committee on new product requests is listed in **Appendix 1**.
The following specific points were highlighted for further consideration:

Nalmefene (Selincro®) 18mg tablets

Nalmefene has been requested for use in adult patients with alcohol dependence that have a high drinking risk level without physical withdrawal symptoms who do not require immediate detoxification but who do require a reduction of alcohol consumption. The group had concerns over the effectiveness of nalmefene compared to counselling alone and it was felt that a reduction of approximately 30 units of alcohol per month did not appear sufficient to justify the significant additional expenditure.
The commissioning for alcohol services is undertaken by local authority public health and there had been no request by them to consider the use of this product.

Decision: Rejected
The request for nalmefene was rejected but the group would be prepared to reconsider the application if an agreed pathway was in place that was supported and funded by local authority public health.

Oxycodone 50mg/ml injection

High strength oxycodone injection has been requested for use in patients requiring high doses which would result in the need for a significant number of ampoules or multiple syringe drivers to be used. Concerns were raised by the formulary subcommittee regarding the risks arising from having multiple strengths of oxycodone injection available for use in the clinical areas and it was agreed that the views of the palliative care teams and those of the accountable officers for controlled drugs within North of Tyne should be sought. This has now been done and fed back to the committee.

Decision: Oxycodone 50mg/ml injection
Approved: approval is for use in controlled circumstances in palliative care patients. It is the responsibility of each individual organisation to ensure appropriate risk management processes are in place.

Domperidone as a galactagogue

There are no licensed galactagogues in the UK. There are some situations, however, where domperidone may be considered to have a role due to it's efficacy and it's low levels of excretion in breast milk.

In circumstances where breast milk supply is of concern,

- In the first instance measures advocated in the Slow Weight Gain Guidance should be followed, including all measures such as ensuring correct positioning, double pumping, etc.
- Infant feeding coordinators support should always be available. If in spite of these measures breast milk supply remains an issue, infant feeding coordinators may suggest that Domperidone could have a role in conjunction with other measures.

The FSC had deferred a decision on this pending receipt of advice from West Midlands and Trent Drug Information Services that this was a recognised use and confirmation of the usual course length. This had now been received and although there is no set timeframe for use it was agreed that generally it would be appropriate to continue for 1-2 weeks after established breast milk production and then reduce. If use of formula increased or was required then it is appropriate to reintroduce the domperidone.

Decision: Domperidone as a galactagogue
Approved

2013/89 Report from the Medicines Guidelines and Use Group
No report is due.

2013/90 Report from the Anti-microbial Chemotherapy subcommittee.
No report is due.

2013/91 Documents previously circulated by e-mail
The NECS MO metoclopramide leaflet for primary care prescribers, as discussed in September 2013/80, was circulated to members to use within their organisations as they see fit.

2013/92 NICE
The following NICE TAGs were noted. The recommendations within them were endorsed by the committee and the North of Tyne Formulary will be updated to reflect these decisions.

NICE Technology Appraisals published in September and October

- TA296: Crizotinib: Lung cancer (non-small-cell, anaplastic lymphoma kinase fusion gene, previously treated) –NICE does not recommend crizotinib for people with a type of advanced non-small-cell lung cancer that is 'ALK-positive' and has been treated before.

It was noted that CDF approvals may differ from NICE but the formulary will reflect the NICE position with CDF use managed separately.

- TA297: Vitreomacular traction - ocriplasmin . Ocriplasmin is recommended as a possible treatment for adults with an eye condition called vitreomacular traction who also have:
  - no epiretinal membrane (a thin layer of scar tissue over their retina, the light-sensitive area at the back of the eye) and
  - a hole (up to 400 micrometers) in the centre of their retina or
  - severe sight problems

2013/93 NHS England Specialised Services Approval
The following NHS England Specialised Service Approvals were noted:
- Stribild - HIV-1 Infection in adults
- Trastuzumab s/c injection

The recommendations within them were noted by the committee and the North of Tyne Formulary will be updated to reflect these decisions.

2013/94 Chair's action

The updated Newer Oral Anticoagulants comparison document had been approved by the chairman and is now available on the website.

2013/95 Any other business

2013/96 Date and time of next meeting

Tuesday 14th January 2014 at 12:30pm
Room 3, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.

21/1/14

Signed: ..... Date: .....

(Chair of the APC)

North of Tyne
Area Prescribing Committee

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

Classification of products:

R = 'RED' drugs for hospital use only
A = 'AMBER' drugs suitable for use under Shared Care arrangements
B = 'BLUE' drugs initiated in secondary care where an information sheet for GPs is recommended

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
Nepafenac (Nevenac®) 1mg/1ml eye drops				Following deferral at the last meeting, the applicant has withdrawn the formulary application
Cosopt® preservative-free eye drops	✔s			Cosopt® Preservative-Free eye drops have been requested for use in patients where allergy develops to preservative-containing drops and who are either intolerant to or non-responsive or partially responsive to other glaucoma drops. Allergy has subsequently been defined as a patient presenting with skin or conjunctival changes. **Decision:** The request for Cosopt® preservative free was approved for use in patients who demonstrate a clear allergy to the preservative as demonstrated by skin or conjunctival changes. Its use should be restricted to this cohort of patients and not for general use in patients who experience stinging as an adverse event.
2) New Requests				
Nalmefene (Selincro®) 18mg tablets		✔		Nalmefene has been requested for use in adult patients with alcohol dependence that have a high drinking risk level without physical withdrawal symptoms who do not require immediate detoxification but who require a reduction of alcohol consumption. The group had concerns over the effectiveness of nalmefene compared to counselling alone and it was felt that the reductions achieved with the addition of nalmefene did not justify the significant additional expenditure. The commissioning for alcohol services is undertaken by local authority public health. **Decision:** The request for nalmefene was rejected but the group would be prepared to reconsider the application if an agreed pathway was in place that was supported and funded by local authority public health.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Combodart® capsules (tamsulosin hydrochloride 400microgram/ dutasteride 500micrograms)		✓		Combodart has been requested for the treatment of lower urinary tract symptoms (LUTS) and the reduction of the risk of acute urinary retention and need for surgery in patients with moderate to severe benign prostatic hyperplasia. Whilst a fixed dose combination may be more convenient for patients there was no good evidence that dutasteride was more effective than finasteride, which is cheaper. **Decision:** The request for Combodart® was rejected on the grounds that there are more cost effective options available on North of Tyne formulary for use in this cohort of patients.
Aclidinium bromide (Eklira Genuair®) 400 microgram inhalation powder	✓			Aclidinium bromide is a long-acting muscarinic antagonist (LAMA) that has been requested as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. Aclidinium has the advantage of having less anticholinergic side effects and gives greater night time control of symptoms. The device is pre-loaded compared to tiotropium and glycopyrronium that require loading before each dose. This may aid compliance in those with dexterity problems. **Decision:** The request for aclidinium bromide was approved as an alternative for patients who are unable to tolerate or use the tiotropium bromide or glycopyrronium bromide inhaler devices. Tiotropium should still be regarded as first choice LAMA on the formulary.
3) New formulations & extensions to use				
Domperidone in breast feeding	✓			Use of domperidone as a galactagogue: This is an unlicensed indication but is standard practice throughout the UK. There is some published evidence to demonstrate its efficacy for this indication and advice was sought from West Midlands and Trent Drug Information Services for Lactation and confirmation of the usual course length. **Decision: Approved**
Oxycodone 50mg/1ml Injection	✓			High strength oxycodone injection is requested for use in patients requiring high doses which would result in need for a significant number of ampoules or multiple syringe drivers to be used. **Decision: Approved** for use in controlled circumstances in palliative care patients. It is the responsibility of each individual organisation to ensure appropriate risk management processes are in place.
Mini TT380 Slimline IUD	✓			**Decision**: The request for the Mini TT380 Slimline IUD was approved for use in women who have a uterine length between 5cm and 6.5cm.
4) Products considered by NESCG and decisions endorsed by APC				
Stribild - HIV-1 Infection in adults	✓ R			**Decision:** Approved in line with NHS England Specialised commissioning criteria

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Trastuzumab s/c injection	✓ R			**Decision:** Approved in line with NHS England Specialised commissioning criteria
5) Products considered by NICE				
TA296: Crizotinib: Lung cancer (non-small-cell, anaplastic lymphoma kinase fusion gene, previously treated)		✓		**Decision:** NICE does not recommend crizotinib for people with a type of advanced non-small-cell lung cancer that is 'ALK-positive' and has been treated before. The formulary will reflect that position.
TA297: Vitreomacular traction - ocriplasmin	✓ R			Ocriplasmin is recommended by NICE as a possible treatment for adults with an eye condition called vitreomacular traction who also have: o no epiretinal membrane (a thin layer of scar tissue over their retina, the light-sensitive area at the back of the eye) and o a hole (up to 400 micrometers) in the centre of their retina or o severe sight problems **Decision:** The formulary will reflect that position.
6) Appeals against earlier decisions by the APC				
Fluticasone 50 microgram / Azelastine 137 microgram (Dymista®) nasal spray		✓		Dymista® nasal spray has been requested to relieve symptoms of moderate to severe seasonal and perennial allergic rhinitis. The application was refused at the September meeting on the grounds that more cost effective options are available for this cohort of patients. **Decision: Refused*:*** The original decision relating to Dymista® was upheld.
7) Miscellaneous decisions by the APC				
Loperamide 2mg oro-dispersible tablets	✓ S			Previously approved for patients with high output stoma. At the point of approval it was intended for inpatient use only and accordingly was given a red status, however it has become apparent that patients with high output stoma are sometimes managed in community following discharge. **Decision:** Loperamide 2mg oro-dispersible tablets are now approved for use in primary care following specialist initiation for patients with high output stoma only.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Memantine 10mg/ml oral solution & Galantamine 4mg/ml oral solution	✓S			These products were given a red status when approved due to concerns around the cost of these compared to the solid dosage forms. Memantine oral solution is now cost neutral compared to the solid formulation. The oral solution is included in NICE TA217 as a treatment option in addition to the other solid formulations. **Decision:** Memantine oral solution is now approved for use in primary care on the condition that it remains cost neutral with its solid dose formulations. Galantamine oral solution was also re-classified due to its inclusion in NICE TA217. However it should only be used if no other preparation is appropriate, due to the additional cost.
Fosfomycin 3g oral sachets [u]	✓S			Fosfomycin 3g sachets are included on the Formulary as a red drug. Oral fosfomycin is occasionally recommended by microbiologists for patients in the community with UTIs caused by multi-resistant organisms. The status will now be changed to allow GP initiation following advice from a microbiologist. **Decision**: Fosfomycin oral sachets should be re-classified to allow for initiation in primary care, but only on the advice of a microbiologist.
Generic sildenafil for pulmonary hypertension	✓R			The group discussed the off label use of generic sildenafil for patients with pulmonary hypertension (PH) instead of the licensed preparation, Revatio®, given the very significant savings this would generate for the NHS. The FSC/APC had been requested to review the safety and efficacy implications of this change. The group discussed the presented evidence and agreed with the conclusion that this change could be supported from a safety and efficacy perspective. **Decision:** The use of generic sildenafil for PH instead of the branded preparation, Revatio®, can be supported from an efficacy and safety perspective.