North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 13th January 2015 at Northumbria House, Cobalt Business Park, North Tyneside

Present:

Anne-Marie Bailey (AMB)	Senior Medicines Optimisation Pharmacist	NECS
Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
Pat Bottrill	Lay Representative	
Russell Buglass(RB)	Community Pharmacist	NoT LPC
David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Sue Dickinson (SD)	Director of Pharmacy	RDTC
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Alexander Dyker (AD)	Consultant Physician	NUTH
Matt Grove (MG)	Consultant Rheumatologist and Head of Service	NHCT
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Peter McEvedy (PMcE)	GP and Prescribing Lead	NHS Northumberland CCG
Helen Seymour (HS)	Senior Medicines Optimisation Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Simon Thomas (STh)	Consultant Clinical Pharmacologist	NUTH
Susan Turner (STu)	Medicines Optimisation Pharmacist	NECS
Neil Watson(NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Steve Williamson(SW)	Consultant Pharmacist in Cancer Services	NHCT/NHSE
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Ian Campbell (IC)	Assistant Director of Pharmacy	NUTH
Janet Kelly	Chief Matron for Community Services	NHCT
Wendy Ross (WR)	GP and APC Representative	NHSNewcastle North & East CCG

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

2015/01 **Declarations of interest**

No relevant declarations.

2015/02 **Appeals against previous decisions**

Avanafil – Mr Trevor Dorkin, Consultant Urologist, Newcastle upon Tyne Hospitals NHS Foundation Trust attended to appeal the previous decision relating to Avanafil use in erectile dysfunction.

Avanafil is the fourth to market phosphodiesterase type 5 (PDE5) inhibitor licensed for the treatment of ED. The committee previously rejected this application on the basis that it believed the mode of action made it akin to sildenafil and could not see sufficient advantages over sildenafil to justify the additional cost.

At the appeal hearing Mr Dorkin outlined various points to the committee including the following:

- He and his colleagues accept that sildenafil should be the first line agent.
- Current pricing of avanafil makes it over £12/month cheaper than tadalafil for standard use and dosing.
- 50-60% of patients respond to sildenafil which leaves a cohort of patients for whom a second line agent is needed.
- He stated that there is less incidence of headache associated with avanafil use than sildenafil use.
- There may be potential benefits over sildenafil in terms of speed of onset, absorption following food intake and duration of action although it was acknowledged that there are no published head to head studies with the other PDE5 inhibitors.
- Tadalafil would still be required on formulary.

Following discussion, the request for avanafil was approved for second line use following failure of, or intolerance to, sildenafil.

The committee has applied conditions to this approval however:

- The use of avanafil should be strictly limited to second line use after intolerance to, or failure of, sildenafil. There should be no first line use based on perceived benefits in terms of onset or duration of action. There was no direct evidence available to confirm clinical superiority v sildenafil.
- The Medicines Guidelines and Use subcommittee of the APC will be asked to audit phosphodiesterase type 5 (PDE5) inhibitor use across the economy in 12 months' time to ensure that the place in therapy, and cost savings projected, reflect this approval.
- The approval for this agent will be reviewed when the price of generic tadalafil is lower than the price of avanafil.

The "SLS" restrictions apply to all erectile dysfunction drugs apart from generic sildenafil, and hence apply to avanafil and tadalafil.

2015/03 **Minutes and decision summary from the meeting held on Tuesday 11th November 2014**

These were accepted as a true record.

2015/04 **Matters arising not on the agenda.**

None

2015/05 Action Log

The action log was reviewed and will be updated to reflect the following progress:

- Hyaluronic acid injection in osteoarthritis – deadline extended to March meeting.
- NICE CG171: Urinary incontinence in women – approved under agenda item 2015/07 – remove from action log.
- Melatonin Blue information leaflet– approved under agenda item 2015/07 – remove from action log.
- Ophthalmic preparations review – specialists currently being consulted.
- Excess treatment costs – DC wrote to the chair of the MO CRG following the last APC meeting to highlight the issues that had been raised in relation to NHS England`s stance on excess treatment costs which may arise from new clinical studies. On the 29th Dec the NHS England Specialised Commissioning team issued a statement to say that additional Guidance is being produced. There is now an interim mechanism in place to address some of the issues raised.

2015/06 Report from the Formulary Sub-committee

Formulary version 5.6 is now available on the APC website.

Minutes and recommendations from the meeting held on 16th December 2014.

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:

Relvar® fluticasone furoate/vilanterol combination inhaler

In May 2014 a request for Relvar Ellipta®, an inhaled corticosteroid (ICS) and long acting beta agonist combination (LABA) inhaler licensed for Asthma (92/22 & 184/22) and COPD (92/22), was refused by the APC due to nationally raised concerns that the blue colour and name could cause patients to mistake this for a "reliever" inhaler. Concerns were also raised that the 92 mcg dose of fluticasone furoate is equivalent to high dose ICS, sitting between step 3 and 4 in the BTS asthma guidelines and this could potentially lead to over dosing. The concerns regarding the livery were subsequently referred to the MHRA.
GSK have now addressed the concerns around the livery by changing the colour from blue to yellow but before approving this product the committee noted that Mr Lowery was in the process of bringing a group together to review the existing formulary choices and new inhalers as a whole. This was a result of the inhaler market becoming increasingly competitive in both the Asthma and COPD fields. It was agreed that this request would be best considered as part of this review. The review outcomes will come straight to the APC for consideration.

Review of calcium & vitamin D3 preparations

Following a recent review of calcium & vitamin D3 preparations, the following decisions were made:

- Accrete D3 caplets should be the first choice preparation - to maximise savings and potentially improve patient compliance.
- Evacal D3 - second choice, offering the choice of a chewable preparation and one that can be taken in patients with peanut or soya allergy.
- Calfovit D3 Sachets to remain on formulary.
- Calcichew D3 Forte and Adcal D3 to be removed from formulary.

NICE diagnostics guidance [DG14] Published date: September 2014

Coagucheck XS and INRatio2 strips to be added to formulary in order to ensure compliance with this Guidance.

2015/07 **Report from the Medicines Guidelines and Use Group**

Draft minutes from the meeting of 19/11/14 were accepted and the following actions taken:

Guidelines approved:

- Non-Surgical Management of Overactive bladder (OAB)

Information leaflets for primary care for approval :

- Melatonin

These will be made available on the APC website.

2015/08 **Report from the Anti-microbial Chemotherapy subcommittee.**

None due

2015/09 **Generic Pregabalin**

The patent for Lyrica® (pregabalin) with respect to generalized anxiety disorder (GAD) and epilepsy expired in July 2014 but there is a second medical use patent protecting pregabalin's use in neuropathic pain which extends to July 2017.

Pfizer have contacted CCGs and community pharmacies to highlight that they believe the supply of generic pregabalin for use in the treatment of pain, whilst the pain patent remains in force in the UK, would infringe Pfizer's patent rights. They are therefore requesting that clinicians prescribe pregabalin by brand (Lyrica®) for neuropathic pain.

The APC supports generic prescribing where clinically appropriate and have issued a document - APC Guideline on Medicines that are Not Suitable for Generic Prescribing (http://www.northoftyneapc.nhs.uk/wp-content/uploads/sites/6/2012/03/APC-Guideline-on-Medicines-that-are-Not-Suitable-for-Generic-Prescribing-January-2014-update-May-2014.pdf) which outlines clinical circumstances where they believe prescribing by brand may be appropriate.

Whilst recognising pharmaceutical company rights with regards to patent protection, the APC does not believe there is any significant clinical difference between the branded and generic pregabalin products. Providing patients have sufficient information provided to them to enable them to take their medication safely, and providing prescribers prescribe in line with their GMC responsibilities around "off-label" prescribing, the APC do not believe it is clinically necessary to prescribe pregabalin by brand name.

Post meeting note: Following the January APC meeting NHS England have been directed through the courts to issue national guidance in relation to Pfizer`s patent rights. This national guidance, available at http://www.england.nhs.uk/wp-content/uploads/2015/03/pregabalin-guidance.pdf supersedes the above statement.

2015/10 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.

- TA323 Erythropoiesis - stimulating agents (epoetin and darbepoetin) for treating anaemia in people with cancer having chemotherapy (including review of TA142)
- TA325 Nalmefene for reducing alcohol consumption in people with alcohol dependence. The formulary entry will include a statement to say that prescribing should be undertaken by a specialist clinician who is providing the appropriate psychosocial support required to achieve best outcomes.
- TA326 Imatinib for the adjuvant treatment of gastrointestinal stromal tumours (review of NICE technology appraisal guidance 196)
- TA327 Dabigatran etexilate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism
- TA328 Idelalisib for treating follicular lymphoma that is refractory to 2 prior treatments (terminated appraisal due to no evidence submission being received)

2015/11 Northern (NHS) Treatment Advisory Group (N-TAG)

Draft minutes from Nov meeting were accepted.

A document entitled "What treatments will NTAG consider? Guidance for Drug and Therapeutics / Area Prescribing Committees, and similar groups" was also received and noted. Some concerns relating to the capacity of N-TAG to meet the number of reviews that may meet the referral criteria were raised but assurance has been given that this will be reviewed if needed.

The following recommendations were noted and the formulary will be updated to reflect these:

- Verteporfin with photodynamic therapy for chronic serous central retinopathy (re-review)
- Biologic drugs for treatment-refractory moderately to severely active ulcerative colitis (UC) in younger patients.

Sativex® oramucosal spray for the management of non–MS pain.

2015/12 NHS England Specialised Services Approval

The following NHS England Specialised Service Approvals were noted:

- SSC1456 - NICE Technology Appraisal 322: Lenalidomide for treating myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality
- SSC 1461 - NICE Technology Appraisal 321: Dabrafenib for treating unresectable or metastatic BRAF V600 mutation-positive melanoma
- SSC 1464 Multiple Sclerosis Risk Sharing Scheme: Price Increase for Glatiramer Acetate (Copaxone made by Teva)"
- SSC 1465: Excess Treatment Costs Associated with AML18 and AML19SSC.

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

Documents previously circulated by e-mail

None

2015/13 Chair's action

- Update to Gender Dysphoria Feminising Hormones Guideline – Approved and on the APC website.

- Regional Antibiotic guidelines – Approved and available on the APC website.

2015/14 **Any other business**

1. Branded generics – It was agreed that the current formulary entry in relation to branded generics should be removed. The APC does not support branded generic prescribing.

2. Biosimilars – SW agreed to undertake some work in relation to biosimilars and present this back to the committee.

2015/15 **Date and time of next meeting**

Tuesday 10th March 2015 at 12:30pm
Room 4, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.

Signed: ..... **Date: 10/3/15**
(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 January 2015.**

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				
No new deferrals				
2) New Requests				
Natamycin 5% eye drops (Natacyn®)	✓ R			Natamycin 5% eye drops (licensed in the USA) have been requested to allow prompt treatment of fungal eye infections with a ready-made, commercially available preparation. Currently amphotericin or voriconazole eye drops are used. These are unlicensed specials and there is a 2 or 3 day delay before treatment can be commenced as these are made to order. Natamycin 5% eye drops are currently first line at Moorfields Eye Hospital and the intention is to initiate patients on natamycin before transferring onto amphotericin or voriconazole eye drops, if required. **Decision:** The request for natamycin 5% eye drops was approved as a red, hospital only drug.
Potassium Chloride 1mmol/ml Carbohydrate free oral solution	✓ R			Carbohydrate free potassium chloride oral solution has been requested for a small number of children with intractable epilepsy being treated with a ketogenic diet. These restricted diets may not have adequate potassium and the carbohydrate load from the licensed oral potassium preparation is too large for some children. **Decision:** The request for potassium chloride carbonate free oral solution was approved as a red, hospital only drug.
3) New formulations & extensions to use				
Dexamethasone injection				Following recent reformulations with changes in name, concentration, storage conditions and presentation a statement will be added to the formulary to convey the changes and prevent confusion.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC1456 - NICE Technology Appraisal 322: Lenalidomide for treating myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality	✓ R			**NHS England position noted**
SSC 1461 - NICE Technology Appraisal 321: Dabrafenib for treating unresectable or metastatic BRAF V600 mutation-positive melanoma	✓ R			**NHS England position noted**
SSC 1464 Multiple Sclerosis Risk Sharing Scheme: Price Increase for Glatiramer Acetate (Copaxone made by Teva)"				**NHS England position noted**
SSC 1465: Excess Treatment Costs Associated with AML18 and AML19				**NHS England position noted**
5) Products considered by NICE				
TA323 Erythropoiesis -stimulating agents (epoetin and darbepoetin) for treating anaemia in people with cancer having chemotherapy (including review of TA142)	✓ R			**The formulary will reflect the TAG.**
TA325 Nalmefene for reducing alcohol consumption in people with alcohol dependence	✓S			**The formulary will reflect the TAG.** Prescribing should be undertaken by a specialist clinician who is providing the appropriate psychosocial support required to achieve best outcomes.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA326 Imatinib for the adjuvant treatment of gastrointestinal stromal tumours (review of NICE technology appraisal guidance 196)	✔ R			**The formulary will reflect the TAG.**
TA327 Dabigatran etexilate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism	✔			**The formulary will reflect the TAG.**
TA328 Idelalisib for treating follicular lymphoma that is refractory to 2 prior treatments (terminated appraisal due to no evidence submission being received)				**The formulary will reflect the TAG.**
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
Verteporfin with photodynamic therapy for chronic serous central retinopathy (re-review)		✔		
Biologic drugs for treatment-refractory moderately to severely active ulcerative colitis (UC) in younger patients.		✔		
Sativex® oramucosal spray for the management of non–MS pain.		✔		

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
7) Appeals against earlier decisions by the APC				
Avanafil	✓			Approved subject to the following: • The use of avanafil should be strictly limited to second line use after intolerance to, or failure of, sildenafil. There should be no first line use based on perceived benefits in terms of onset or duration of action. There was no direct evidence available to confirm clinical superiority v sildenafil. • The Medicines Guidelines and Use subcommittee of the APC will be asked to audit phosphodiesterase type 5 (PDE5) inhibitor use across the economy in 12 months' time to ensure that the place in therapy and cost savings projected have been realised. • The approval for this agent will be reviewed if the price of tadalafil becomes lower than the price of avanafil.
8) Miscellaneous decisions by the APC				
Review of calcium and vitamin D_3 preparations	See notes			Following a review of calcium and vitamin D_3 preparations the following was agreed: • Accrete D_3® caplets as first line preaparation • Evacal D_3® tablets as a chewable option as second line and also to be used in patietns with peanut and soya allergy • Calfovit® sachets to remain on formulary • Calcichew D_3 Forte® and Adcal D_3® to be removed from the formulary
Chlorhexidine solutions.	See notes			Following the recent MHRA drug safety updates, a warning will be added to the formulary as a reminder of the risk of chemical burns in premature infants
INR testing	✓			Coagucheck XS and INRatio2 test strips to be added to the formulary in order to meet the requirements of NICE diagnostics guidance [DG14] Published date: September 2014