North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 10th March 2015 at Northumbria House, Cobalt Business Park, North Tyneside

Present:

Anne-Marie Bailey (AMB)	Senior Medicines Optimisation Pharmacist	NECS
Pat Bottrill	Lay Representative	
David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Helen Coundon	GP and Prescribing Lead	NHS North Tyneside CCG
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
Wendy Ross (WR)	GP and APC Representative	NHSNewcastle North & East 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

Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
Russell Buglass(RB)	Community Pharmacist	NoT LPC

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

2015/16 **Declarations of interest**

No relevant declarations.

2015/17 **Appeals against previous decisions**

None

2015/18 **Minutes and decision summary from the meeting held on Tuesday 13th January 2015**

These were accepted as a true record.

It was agreed that a post meeting note should be added to clarify that the statement relating to pregabalin has been superseded by NHS England advice.

2015/19 **Matters arising not on the agenda.**

None

2015/20 **Action Log**

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

- Hyaluronic acid injection in osteoarthritis –NICE no longer recognise a role for this, therefore the committee agreed a 2 week deadline for comments from specialists at which point chair`s approval would be taken to remove this from the formulary unless any valid comments challenging this were received.
- Ophthalmic preparations review – specialists currently being consulted.
- Inhaler review – a working group has now met and recommendations will come to the committee via the FSC.

2015/21 **Report from the Formulary Sub-committee**

Formulary version 5.7 is now available on the APC website.

Minutes and recommendations from the meeting held on 12th February 2015.

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:

Peginterferon Peginterferon beta-1a 125microgram pre-filled injection (Plegrdy®)

It has been confirmed that NHS England will fund the use of peginterferon beta-1a but there is no formal policy in place. The NoT APC was asked to review this product for the purposes of clinical governance only. Peginterferon beta-1a has been requested for the treatment of relapsing-remitting multiple sclerosis in patients wishing to start injectable therapy or who have not tolerated first-line oral therapies. The reduction in the rate of relapses is in keeping with the beta interferons but with reduced frequency of administration.

Decision: The request for peginterferon was approved from a clinical governance perspective.

Nortriptyline 10mg & 25mg tablets

Nortriptyline has been requested for specialist use in patients for headache / migraine prophylaxis and for the treatment of neuropathic pain. This is as a second line agent to amitriptyline on the grounds it has less anticholinergic side effects and it is less sedating. There is a lack of evidence to support its use and it is very expensive compared to the other treatment options. It was

agreed that imipramine was a more appropriate choice as a second line agent for these indications. The committee agreed that where patients were stable on previously started nortriptyline it would not advocate an active switching programme onto an alternative agent. Where review was required on clinical grounds, however, and treatment was felt to be sub-optimal, consideration would be given at that point to an appropriate formulary approved alternative.

Decision: The product was rejected due to a lack of evidence to support its use and the fact that it is more expensive than alternative treatment options. The approved indications for imipramine will be extended to cover use in these circumstances.

2015/22 Report from the Medicines Guidelines and Use Group

Draft minutes from the meeting of 28/01/15 were noted and accepted. The following actions were taken:

Guidelines approved (via chairs action):

- FATS 7
- Guidance for managing the Menopause

Information leaflets for primary care for approval :

- Agomelatine - approved.

These will be made available on the APC website.

2015/23 Report from the Anti-microbial Chemotherapy subcommittee.

None due

2015/24 Generic Pregabalin

The patent for Lyrica® (pregabalin), with respect to generalised 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. At the January APC meeting the committee made a statement relating to this.

The committee accept that this statement has now been superseded by NHS England advice which was issued at the direction of the courts. See 2015/18 and http://www.england.nhs.uk/wp-content/uploads/2015/03/pregabalin-guidance.pdf

MGUG is due to consider guidance at the March meeting, which includes the appropriate use of medication, for the treatment of neuropathic pain. It was agreed that DC could take chair's action to approve this guidance if MGUG raised no concerns. This would help support the appropriate management of such patients.

2015/25 Biosimilars

A paper was presented for consideration. Following discussion it was agreed that the author would amend the recommendations and re-circulate to members for approval.

2015/26 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.

- TA329 Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262)
- TA330 Sofosbuvir for treating chronic hepatitis C
- TA331 Simeprevir in combination with peginterferon alfa and ribavirin for treating genotypes 1 and 4 chronic hepatitis C
- TA332 Sipuleucel-T for treating asymptomatic or minimally

symptomatic metastatic hormone-relapsed prostate cancer
- TA333 Axitinib for treating advanced renal cell carcinoma after failure of prior systemic treatment
- TA334 Regorafenib for metastatic colorectal cancer after treatment for metastatic disease (terminated appraisal)

2015/27 Northern (NHS) Treatment Advisory Group (N-TAG)

The February meeting was cancelled.

2015/28 NHS England

The following NHS England communications were noted:

- NHS England Clinical Commissioning Policy: Use of defibrotide in severe veno-occlusive disease following stem cell transplant
- NHS England Clinical Commissioning Policy: Dolutegravir for treatment of HIV-1 in adults and adolescents
- NHS England Clinical Commissioning Policy: Glucarpidase for the urgent treatment of methotrexate-induced renal dysfunction
- SSC 1466: Renal Transplant CRG - Guidance on Prescribing of Immunosuppressive Therapy for Kidney Transplant Recipients
- SSC 1467: Clinical Commissioning Policy Statement: Simeprevir for treating Genotype 1 chronic hepatitis C A02/PS/C
- SSC 1568: NICE Technology Appraisal 326: Imatinib for the adjuvant treatment of gastrointestinal stromal tumours (review of TA196)SSC

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

2015/29 Documents previously circulated by e-mail

NHS England consultation on selected specialised services - noted.

2015/30 Chair's action

- Update to FATS Guidance. FATS 7 approved and on the APC website.
- Menopause– Approved and available on the APC website.
- Updated oral anticoagulant comparison guide available on website

2015/31 Any other business

1. Duraphat toothpaste – This product was previously approved with a restriction to dental prescribing only. It was agreed that this restriction should be removed to allow ongoing prescribing in primary care following specialist initiation for fluoride supplementation in line with the DOH guideline for 'Delivering better oral health'.

2. Bile Acid Sequestrants – Following publication of NICE CG 181, Lipid modification, there will be a review of the formulary position of some agents used in lipid lowering. MG requested endorsement of the continued role of bile acid sequestrants as an antidote to leflunomide. The committee accepted this.

2015/32 Date and time of next meeting

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

Signed: ..... **Date:** 12/5/15 .....
(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 10th March 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				
Peginterferon beta-1a 125microgram pre-filled injection (Plegrdy®)	✓ R			It has been confirmed that NHS England will fund the use of peginterferon beta-1a but there is no formal commissioning policy in place. The NoT APC was asked to review this product for the purposes of clinical governance only. Peginterferon beta-1a has been requested for the treatment of relapsing-remitting multiple sclerosis in patients wishing to start injectable therapy or who have not tolerated first-line oral therapies. The reduction in the rate of relapses is in keeping with the beta interferons but with reduced frequency of administration. **Decision:** The request for peginterferon was approved from a clinical governance perspective.
Temocillin 1g injection (Negaban®)	✓ R			Temocillin has been requested for the treatment of susceptible Gram-negative bacteria to reduce the usage of broad spectrum agents, such as the carbapenems. Treatment will be guided by culture and sensitivity testing and on the advice of microbiologists. **Decision:** The request for temocillin injection was approved. Its use will be restricted to hospitals on the advice of microbiologists.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Nortriptyline 10mg & 25mg tablets		✓		Nortriptyline has been requested for specialist use in patients for headache / migraine prophylaxis and for the treatment of neuropathic pain. This is as a second line agent to amitriptyline on the grounds it has less anticholinergic side effects and it is less sedating. It was noted that there is a lack of evidence to support its use and it is very expensive compared to other treatment options. It was agreed that imipramine was a more appropriate choice as a second line agent for these indications.
Imipramine 10mg and 25mg tablets	✓ C			**Decision:** The request for nortriptyline was refused on the grounds that the costs are not justifiable in relation to available evidence. Imipramine was approved as the second line tricyclic antidepressant for these indications.
3) New formulations & extensions to use				
Dexmedetomidine 100mcg/ml solution for infusion (Dexdor®)	✓ R			Dexmedetomidine has been requested for additional indications, to assist in the rapid weaning in patients deemed suitable for respiratory weaning and where a reduction in support has stalled due to neurological symptoms of delirium and/or agitation. Use should be restricted to patients who are difficult to sedate or have failed conventional methods of treatment. **Decision:** The approved indications for dexmedetomidine use have been extended to include patients who are difficult to sedate e.g. patients who have taken MDMA/PMA/"legal highs" or have pre-existing drug or alcohol dependence or who have failed conventional methods of treatment.
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC 1466: Renal Transplant CRG - Guidance on Prescribing of Immunosuppressive Therapy for Kidney Transplant Recipients				**NHS England position noted**
SSC 1467: Clinical Commissioning Policy Statement: Simeprevir for treating Genotype 1 chronic hepatitis C A02/PS/C				**NHS England position noted**
SSC 1568: NICE Technology Appraisal 326: Imatinib for the adjuvant treatment of gastrointestinal stromal tumours (review of TA196)				**NHS England position noted**

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
NHS England Clinical Commissioning Policy: Use of defibrotide in severe veno-occlusive disease following stem cell transplant				**NHS England position noted**
NHS England Clinical Commissioning Policy: Dolutegravir for treatment of HIV-1 in adults and adolescents				**NHS England position noted**
NHS England Clinical Commissioning Policy: Glucarpidase for the urgent treatment of methotrexate-induced renal dysfunction				**NHS England position noted**
5) Products considered by NICE				
TA329 Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262)				**The formulary will reflect the TAG.**
TA 330 Sofosbuvir for treating chronic hepatitis C				**The formulary will reflect the TAG.**
TA 331 Simeprevir in combination with peginterferon alfa and ribavirin for treating genotypes 1 and 4 chronic hepatitis C				**The formulary will reflect the TAG.**
TA 332 Sipuleucel-T for treating asymptomatic or minimally symptomatic metastatic hormone-relapsed prostate cancer				**The formulary will reflect the TAG.**
TA 333 Axitinib for treating advanced renal cell carcinoma after failure of prior systemic treatment				**The formulary will reflect the TAG.**

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA 334 Regorafenib for metastatic colorectal cancer after treatment for metastatic disease (terminated appraisal)				
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
No meeting				
7) Appeals against earlier decisions by the APC				
None				
8) Miscellaneous decisions by the APC				
Colecalciferol capsules 20,000iu				There are now two new licensed high dose 20,000iu colecalciferol capsules available on the market with more expected. It was agreed that as these licensed products were now available the unlicensed status should be removed from the formulary to allow for generic prescribing. Pharmacies and dispensing practices should supply a licensed product in preference to an unlicensed one in line with MHRA Guidance. The 25,000iu (InVita D3®) product will also now be removed from the formulary as the licensed capsule forms were deemed more appropriate.
Duraphat toothpaste				Removal of restriction to dental prescribing only to allow ongoing prescribing in primary care following specialist initiation for fluoride supplementation in line with the DOH guideline for 'Delivering better oral health'. r to be replaced with s.