North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 9th September 2014 at Northumbria House, Cobalt Business Park, North Tyneside

Present:

Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Ian Campbell (IC)	Assistant Director of Pharmacy	NUTH
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
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) (minute taker)	Senior Medicines Optimisation Pharmacist	NECS
Simon Thomas (STh)	Consultant Clinical Pharmacologist	NUTH
Sarah Tulip (for AMB)	Medicines Optimisation Pharmacist	NECS
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Anne-Marie Bailey (AMB)	Senior Medicines Optimisation Pharmacist	NECS
Susan Turner (STu)	Medicines Optimisation Pharmacist	NECS

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

2014/62 Declarations of interest

None

2014/63 Public Health representation

Dr Sue Gordon has resigned from the APC. Thanks for her contribution in previous years have been extended to her via letter from DC. Dr Eugene Milne (Director of Public Health, Newcastle Local Authority) has agreed to attend relevant meetings and liaise with colleagues across all North of Tyne LAs.

2014/64 Appeals against previous decisions

Movicol liquid

Julie Cummings and Morag Bagnall (Community Matrons, NHCT, with a responsibility for supporting nurses working in care homes in Northumberland) presented their findings from an audit which demonstrated that care home residents who were finding Laxido/Movicol sachets difficult to tolerate, and were on multiple other laxatives, were able to have their laxative regime simplified with better outcomes if the sachets were changed to Movicol liquid. They were in the process of compiling data to demonstrate that their interventions had reduced hospital admissions for constipation. The majority of patients that had been reviewed had dementia. They estimated that 75% of patients were switched from Laxido to Movicol liquid had their other laxatives stopped. Comments were made that significant numbers of nursing home patients can be managed by increasing their fluid intake. JK reassured the group that the community matrons are addressing standards of care within nursing homes.

Decision: Approved
The request for Movicol liquid was approved as a second line macrogol laxative for care home residents only where the sachets are not tolerated. Community Matrons will be asked to provide audit data regarding admissions avoidance due to constipation to a future MGUG meeting.

2014/65 Minutes and decision summary from the meeting held on Tuesday 8th July 2014

These were accepted as a true record.

2014/66 Matters arising not on the agenda.

- Tocilizumab impact assessment. This had been circulated and received by all CCGs who were all now in a position to approve the application

Decision: Approved
The request for Tocilizumab s/c was approved for use in rheumatoid arthritis in line with the IV approval NICE TA 247.

2014/67 Action Log

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

- Domperidone use as a galactagogue (2014/28) – SD has contacted UKMI regarding the appropriate duration of domperidone use for this indication. They confirmed that their recommendation was based on MHRA advice relating to treatment of nausea and vomiting and that this was an arbitrary limit. It was agreed that continued use for this indication was appropriate in certain patients where a risk assessment of the likelihood of a cardiovascular event was made. The formulary will be documented to reflect this. ML will compile a briefing paper on the treatment of nausea and vomiting to be presented to the FSC at a later date.
- NICE CG171: Urinary incontinence in women – see update under 2014/68.
- New product application – Deadline deferred to 11.11.14.
- Lay representation – Pat Bottrill has agreed to join the committee.
- Public health representation – Dr Eugene Milne to join APC
- Tocilizumab – completed – see 2014/66.
- Hyaluronic acid injection – rheumatologists do not use this product. ML to ask orthopaedic surgeons for their feedback for 11.11.14.

2014/68 Report from the Formulary Sub-committee

Formulary version 5.4 is now available on the APC website.

Minutes and recommendations from the meeting held on 7th August 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:

Tocofersolan 50mg/ml oral solution (Vedrop®)

Tocofersolan oral solution has been requested to treat vitamin E deficiency in children due to fat malabsorption syndromes. It was felt that IM preparations give better availability but currently there are issues obtaining a supply. It was confirmed that vitamin E deficiency is responsible for severe and evolving neurological disorders which, uncorrected, can confine children to a wheelchair by adolescence.

Decision: Approved
The request for tocofersolan was approved for the treatment of vitamin E deficiency in children due to fat malabsorption syndromes. Treatment will be initiated by specialists .

Brimonidine 0.33% gel (Mirvaso®)

Brimonidine gel has been requested for the treatment of moderate to severe persistent erythema of rosacea, which is categorised as causing psychological or social distress. Brimonidine gel has been demonstrated as being effective although the improvement in some patients is modest. The potential numbers of patients seeking treatment could be large and it was agreed that use would be restricted to specialist initiation for severe rosacea. Following specialist review of effectiveness, treatment can continue in primary care.

Decision: Approved
The request for Brimonidine was approved for specialist initiation for the treatment of severe rosacea. Following specialist review of effectiveness, primary care can continue supply.

Melatonin review

Following concerns around high expenditure, and the evidence base, NTW have reviewed the use of melatonin. The review recommended the use of three products

- Melatonin 2mg MR tablets – first line
- Melatonin 2mg MR tablets (crushed) – second line
- Melatonin 5mg/5ml oral solution – third line.

Usage would be monitored on a quarterly basis to ensure appropriate use.

Decision: Approved
The formulary will be amended to include the above three formulations of melatonin as the only formulations approved North of Tyne. The Blue leaflet will be revised.

NICE CG171: Urinary incontinence in women

Simon Thomas gave a brief update on the outputs from a meeting he chaired on 10th July, attended by urologists, GPs and pharmacists, to discuss implementation of the drug recommendations outlined in NICE CG171.

The drug recommendations arising from that meeting were endorsed by the

committee and will be reflected in the formulary.
Some more detailed guidance around primary care assessment and referral criteria will be produced and published on the APC website once complete.

2014/69 Report from the Medicines Guidelines and Use Group

DC had written to Dr M Wright and Dr S Summers requesting information regarding any developments within North Tyneside and Newcastle CCGs regarding shared care for immune modifying drugs for patients with non-rheumatological disease. Newcastle North and East and Newcastle West CCGs have this in their commissioning intentions for 14/15. North Tyneside CCG are aware of this issue and are exploring the commissioning implications.
Draft minutes from the meeting of 30/7/14 were accepted and the following actions taken:
Guidelines approved:

- Guideline for management of erectile dysfunction in adults ≥ 18 years
- Guidelines for the use of feminising hormone therapy in gender dysphoria
- Newcastle, North Tyneside and Northumberland Guidelines for the Management of Adults with Asyptomatic Liver Function Abnormalities
- Seven Day prescriptions
- Guidelines for the management of Patients with Swallowing Difficulties

Information leaflets for primary care approved :

- Buccal Midazolam (Midazolam Hydrochloride 5mg/ml) – Buccolam®
- Buccal Midazolam (Midazolam maleate 10mg/ml) – Epistatus®

Shared Care Guidelines approved:

- Vigabatran

2014/70 Report from the Anti-microbial Chemotherapy subcommittee.

No report due.
HS briefed the committee about the development of a region wide primary care guideline which has had the support of Public Health England and has involved both the regional microbiologists group and the regional antimicrobial pharmacists network. It was agreed that once the North of Tyne subcommittee are happy with the guideline DC will take Chair's action to approve.

2014/71 Documents previously circulated by e-mail

None

2014/72 NICE

Noted that NHSE will only fund NICE approved medicines 90 days after TAs are published, something which the committee has challenged unsuccessfully previously, therefore it was agreed that trust pharmacies will operate an internal mechanism to ensure that products approved by NICE and funded by NHSE will only be dispensed once funding arrangements are in place.
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.

- TA 316 Prostate cancer (hormone relapsed, metastatic) - enzalutamide (after docetaxel)
- TA 317 Acute coronary syndrome - prasugrel with PCI (review of TA182)
- TA 318 Lubiprostone for treating chronic idiopathic constipation
- TA 319 Melanoma (previously untreated unresectable stage III or IV) – ipilimumab
- TA 320 Dimethyl fumarate for treating relapsing- remitting multiple sclerosis

The following NICE guidelines were noted, all drugs recommended were already approved North of Tyne.

- CG 181 Lipid modification (update)
- CG 182 Chronic kidney disease (update)

2014/73 **Northern (NHS) Treatment Advisory Group (N-TAG)** Simon Thomas gave a verbal update to the group from the meeting that took place on 9th September 2014. A decision summary will be available on the group's website within 20 days of meeting (www.ntag.nhs.uk/). In summary:

- Aripiprazole LAI and Paliperidone LAI. The decision has been deferred until a protocol/pathway is received from the mental health trusts across the region outlining how they plan to use these, taking into consideration cost effectiveness and affordability.
- Lucentis/Avastin – NTAG endorsed the previously agreed NETAG decision that Avastin could be used outside of its licensed indication in ARMD as there was further data on safety now available.
- The group agreed the use of sequential pharmacological therapies in the management of macular oedema secondary to retinal vein occlusion.
- EMA review of Ulipristal - no changes to the previous NETAG recommendation were necessary.

2014/74 **NHS England Specialised Services Approval**

The following NHS England Specialised Service Approvals were noted:

- SSC1433: Alemtuzumab: All MS patients who meet the NICE criteria for alemtuzumab will receive funding from August 27 2014.
- SSC1434: Commissioning of Subcutaneous Rituximab
- SSC1437: Medicines not reimbursed through national prices: Indications commissioned by NHS England Specialised Services
- SSC1438: Commissioning of Abiraterone
- SSC1439: NHS England will commission enzalutamide from 21st October 2014 in line with NICE TAG 316. Enzalutamide will continue to be funded from the Cancer Drugs Fund until that date.
- SSC1440: All metastatic melanoma patients who meet the NICE criteria for ipilimumab will receive funding from October 21 2014.
- SSC1443: Oncotype DX® commissioning arrangements

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

2014/75 **Chair's action**

None

2014/76 **Any other business**

Sarah Chandler asked the committee if anyone was aware of whether NICE were progressing with publication of a generic patient alert card for the NOACs. SD agreed to confirm with NICE

2014/77 **Date and time of next meeting**

Tuesday 11th November 2014 at 12:30pm
Room 4, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.

Signed: ..... **Date:** 11/11/14

(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 9th September 2014.**

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				
Dexmedetomidine 100mcg/ml solution for infusion (Dexdor®)	✓ R			The request for dexmedetomidine was previously deferred until there was further clarification on advantages over midazolam and propofol and a more clearly defined position for use. **Decision: Approved** Dexmedetomidine was approved for • TBI patients, no respiratory problems but need to have prolonged ventilatory support due to severe agitation, confusion and requirement for propofol/midazolam. • Young, male overdose of MDMA/PMA/'legal' highs who have prolonged ventilation for reasons of lack of potent enough sedative agent not causing respiratory depression It will be listed as a Red drug.
Tocilizumab 162mg subcutaneous injection (RoActemra®)	✓ R			Tocilizumab subcutaneous injection (SC) has recently been licensed for rheumatoid arthritis. The SC preparation has the advantage of being able to be self-administered, and therefore potentially delivered via Homecare arrangements. The application was previously clinically approved but an impact assessment for CCGs was requested prior to commencement of service. **Decision: Approved** The request for Tocilizumab s/c was approved for use in rheumatoid arthritis in line with the IV approval NICE TA 247.
Emerade® 500 microgram auto-injector (Adrenaline 1:1000)			✓	Emerade® 500 had previously been requested the NUTH community dental team for use in their anaphylaxis boxes instead of ampoules The request was deferred until further clarity is sought on the appropriateness of continued use of the ampoules and this is still awaited.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
2) New Requests				
Enoximone 5mg/ml injection (Perfan ®)			✓	Enoximone has been requested for the medium to long term treatment of severe congestive heart failure in children to try and wean them from IV milrinone. **Decision: Deferred** The request for enoximone injection was deferred pending confirmation of bioavailability and pharmacokinetics in children.
Prednisolone 1mg M/R Tablets (Lodotra ®)		✓		Prednisone M/R tablets have been requested for the management of early-morning nausea, lethargy and inertia in patients with adrenal insufficiency. **Decision: Refused** The request for prednisone M/R tablets was refused on the grounds there is very limited evidence supporting its use.
Tocofersolan 50mg/ml oral solution (Vedrop ®)	✓			Tocofersolan oral solution has been requested to treat vitamin E deficiency in children due to fat malabsorption syndromes. **Decision: Approved** The request for tocofersolan was approved for the treatment of vitamin E deficiency in children due to fat malabsorption syndromes. Treatment is to be initiated by specialists .
Umeclidinium/vilanterol 55/22 microgram inhaler (Anoro Ellipta ®)			✓	Anoro Ellipta® has been requested for the treatment of COPD in adults. This is the first to market LAMA/LABA combination. **Decision: Deferred** The request for Anoro Ellipta® was deferred for up to 12 months. This decision will be reviewed once other LAMA/LABA combinations have come to market.
Brimonidine 0.33% gel (Mirvaso®)	✓			Brimonidine gel has been requested for the treatment of moderate to severe persistent erythema of rosacea, which is catergorised as causing psychological or social distress. **Decision: Approved** The request for Brimonidine was approved for specialist initiation for the treatment of severe rosacea. Following specialist review of effectiveness, primary care can continue supply.
3) New formulations & extensions to use				
Lipegfilgrastim [Lonquex ®]	✓ R			**Decision: Approved** Lipegfilgrastim [Lonquex ®]) is a generic long-acting GCSF which is approved for use, where possible, in place of pegfilgrastim. It will be a Red drug.
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC1433: Alemtuzumab	noted			All MS patients who meet the NICE criteria for alemtuzumab will receive funding from August 27 2014. The formulary will reflect the NHS England Specialised Services circular position.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
SSC1434: Commissioning of Subcutaneous Rituximab	noted			The formulary will reflect the NHS England Specialised Services circular position.
SSC1437: Medicines not reimbursed through national prices	noted			
SSC1438: Commissioning of Abiraterone	noted			The formulary will reflect the NHS England Specialised Services circular position.
SSC1439: Enalzutamide	noted			NHS England will commission enzalutamide from 21st October 2014 in line with NICE TAG 316. Enzalutamide will continue to be funded from the Cancer Drugs Fund until that date.
SSC1440: Ipilimumab	noted			All metastatic melanoma patients who meet the NICE criteria for ipilimumab will receive funding from October 21 2014.
SSC1443: Oncotype DX® commissioning arrangements	noted			
5) Products considered by NICE				
TA 316 Prostate cancer (hormone relapsed, metastatic) - enzalutamide (after docetaxel)	noted			The formulary will reflect the NICE position
TA 317 Acute coronary syndrome - prasugrel with PCI (review of TA182)	noted			The formulary will reflect the NICE position
TA 318 Lubiprostone for treating chronic idiopathic constipation	noted			The formulary will reflect the NICE position
TA 319 Melanoma (previously untreated unresectable stage III or IV) – ipilimumab	noted			The formulary will reflect the NICE position. See SSC1440.
TA 320 Dimethyl fumarate for treating relapsing-remitting multiple sclerosis	noted			The formulary will reflect the NICE position
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
Lucentis/Avastin	noted			N- TAG endorsed the previously agreed NETAG decision that Avastin could be used outside of it's licensed indication in ARMD as there was further data on safety now available.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Sequential pharmacological therapies in the management of macular oedema secondary to retinal vein occlusion	noted			The recommendation includes dexamethasone steroid implant Ozurdex®.
Aripiprazole LAI and Paliperidone LAI.			noted	The decision has been deferred until we receive a protocol/pathway from the mental health trusts across the region outlining how they plan to use these, taking into consideration cost effectiveness and affordability.
7) Appeals against earlier decisions by the APC				
Movicol liquid	✓			Movicol liquid was requested for care home patients on multiple oral laxatives who have poor compliance and require enemas to alleviate constipation. It was previously felt there was not sufficient advantage over Laxido sachets to justify a 30% cost increase however additional data was presented on appeal. **Decision: Approved** The request for Movicol liquid was approved as a second line macrogol laxative for care home residents only where the sachet formulation is not tolerated. Community Matrons are requested to provide audit data regarding admissions avoidance due to constipation to a future MGUG meeting.
8) Miscellaneous decisions by the APC				
Melatonin review	See notes			The review recommended the use of three products - Melatonin 2mg MR tablets – first line - Melatonin 2mg MR tablets (crushed) – second line - Melatonin 5mg/5ml oral solution – third line. **Decision: Approved** The formulary will be amended to include the above three formulations of melatonin as the only formulations approved North of Tyne. The Blue leaflet will be revised.
Intravenous dantrolene	See notes			There is a risk of skin and injection site reactions from un-dissolved crystals. The use of a filter needle when drawing up reconstituted dantrolene solution and increased vigilance is recommended. The formulary will be updated accordingly
Ropinirole for the treatment of restless legs syndrome	✓			Rotigotine is on the formulary as a second line agent for restless legs syndrome, however there is no specified first line agent. Ropinirole is recommended for the treatment of restless legs syndrome by CKS, therefore the committee agreed to add ropinirole to the formulary as the first line agent for this indication, and update the blue information leaflet accordingly.