North of Tyne
Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 8th July 2014 at Northumbria House, Cobalt Business Park, North Tyneside

Present:

Anne-Marie Bailey	Senior Medicines Optimisation Pharmacist	NECS
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
Helen Coundon	GP and Prescribing lead	NHS North Tyneside CCG
Sue Dickinson	Director of Pharmacy	RDTC
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTWT
Alexander Dyker	Consultant Physician	NUTH
Matt Grove	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	GP and APC Representative	NHSNewcastle North & East CCG
Simon Thomas	Consultant Clinical Pharmacologist	NUTH
Susan Turner (STu) (Professional Secretary)	Medicines Optimisation Pharmacist	NECS
Hilary Wynne (HW)	Consultant Physician/Chair of NUTH D&T panel	NUTH

Apologies

Russell Buglass	Community Pharmacist	NoT LPC
Sue Gordon (SG)	Consultant in Public Health	NHS England
David Jones	GP and APC Representative	NHS Newcastle West CCG
Tamsin Oswald (TO)	Consultant Microbiologist	NHCT
Helen Seymour	Senior Medicines Optimisation Pharmacist	NECS
Neil Watson (NW)	Clinical Director of Pharmacy and Medicines Management	NUTH

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

2014/46 **Declarations of interest**
None

2014/47 **Appeals**
No appeals.

2014/48 **Minutes and decision summary from the meeting held on Tuesday 13th May 2014.**
These were accepted as a true record.

2014/49 **Matters arising not on the agenda.**
None

2014/50 **Action Log**
The action log was reviewed and will be updated to reflect the following progress:

- Linaclotide blue information sheet – presented today for consideration (see 2014/53).
- C Diff Assessment Tool – approved via chair's action.
- Domperidone use as a galactagogue (2014/28) – Following the MHRA publication, UKMi has published some additional advice. SD will contact them to clarify specifics in terms of duration of treatment when used as a galactagogue. The formulary will be annotated in line with the MHRA advice and will link to the UKMi additional information.
- NICE CG171: Urinary incontinence in women - Meeting arranged for 10/7/14 with representation from primary and secondary care.
- Dihydrocodeine - presented today for consideration.
- Lay representation – work to find a replacement member is progressing.

2014/51 TO has indicated her intention to resign from the committee. The chair will ask her, in her continuing role on the antimicrobial chemotherapy subcommittee, to nominate a suggested replacement member. The committee wished to thank her for her support and valuable input during her tenure.

2014/52 **Report from the Formulary Sub-committee**
Formulary version 5.3 is now available on the APC website.
Minutes and recommendations from the meeting held on 12th June 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:

Dexmedetomidine
Dexmedetomidine is significantly more expensive than midazolam and propofol but savings may be seen through a reduction in the need for mechanical ventilation. It was felt that there was a need for further clarity around clearly defining the positioning of dexmedetomidine including explaining advantages over propofol.

Decision:Deferred
The request for dexmedetomidine was deferred until there was further clarification on advantages over midazolam and propofol and a more clearly defined position for use.

Tocilizumab 162mg subcutaneous injection
Tocilizumab 162mg subcutaneous (SC) injection has recently been licensed for rheumatoid arthritis (RA) on the basis of non-inferiority trials comparing it to the IV formulation. The IV formulation is NICE approved for RA, however the SC formulation has advantages in that it can be self-administered, and hence

delivered via Homecare arrangements. There were concerns that despite the significant savings from a reduction in hospital IV administration day case charges in these patients, and VAT savings, there could be increased usage of Tocilizumab overall, in preference to other biologics approved for RA. MG informed the committee that NICE have approved tocilizumab as either a 1st or 3rd line biologic in RA. Currently it's mostly used 3rd line because Rheumatologists have long experience of anti-TNF agents and prefer these in most cases; furthermore there are some additional contraindications and concerns over tocilizumab (principally patients with liver function abnormalities, diverticulitis and raised cholesterol levels) that aren't as significant for anti-TNF. There is a small subset of patients, mostly with very high inflammatory markers and very poorly controlled disease, which may do better on tocilizumab and where this may be preferred first line. It is expected that there will be an increased use of tocilizumab 1st line with time, and availability of sc dosing will assist this. If sc tocilizumab is available this increase will be cost-neutral, where activity charges are on a cost per case basis, because there will be a consequent decrease in 1st line anti-TNF use, and the drug costs are very comparable. If the sc formulation is not available, increasing 1st line tocilizumab use will result in a large increase in day case iv infusion costs. CCGs requested some additional information relating to projected numbers of patients who would be moved from day case to Homecare arrangements in order to assist contractual and financial planning. Concerns were raised with regards to current national issues with Homecare arrangements and this would be taken into account before any arrangement was entered into.

Decision: Deferred
Clinically approved but an impact assessment for CCGs is needed prior to commencement of service.

Emerade® 500 microgram auto-injector (Adrenaline 1:1000)
It was agreed Emerade® 500mcg should be added to the formulary for specialist initiation in patients with a BMI of >40 or those patients who have required more than one adrenaline auto-injector (300 microgram) previously, to control symptoms with specialist initiation.
Emerade© 500microgram has also been requested by the NUTH community dental team for use in their anaphylaxis boxes instead of adrenaline 1mg/ml ampoules. This was on the grounds that dentists do not routinely give IM injections and would therefore prefer to use auto-injectors.

Decision: Approved for patients with a BMI>40 or those patients who have required more than one adrenaline auto-injector (300 microgram) previously, to control symptoms with specialist initiation.
Deferred for dental team until further information is received.

Levonelle©
Data has been submitted to the EMA, with a view to changing the SPC, that suggests the efficacy of levonorgestrel 1500 micrograms (Levonelle©) is reduced in women weighing over 75 kg. Previously NETAG (now NTAG) advised that Levonelle© is first line choice for women up to 72 hours then Ulipristal can be used between 72 and up to 120 hours. The group noted that current Faculty of Sexual and Reproductive Healthcare (FSRH) guidance (November 2013) recommends no change in practice until further data becomes available. This was on the basis that whilst the data indicated an increased risk

of pregnancy the differences were not statistically significant. Concerns were raised that even if the available evidence did not strongly support a change in practice this should be considered given the implications of unwanted pregnancies. It was agreed that the formulary should remain unchanged until a clear directive is received from regulators. PGDs should reflect the formulary status.

2014/53 Report from the Medicines Guidelines and Use Group

Draft minutes from the meeting of 21/5/14 were accepted and the following actions taken:

Guidelines for approval:

- Management of angina due to coronary artery disease – clarification to be sought on the role of glucose vs HbA1c testing. Otherwise approved.
- Gluten Free food guideline - approved
- North of Tyne and Gateshead ENT Guidelines – these guidelines are dated May 2013. They were approved subject to confirmation by the author that the guideline is still relevant at the date of approval.

It was noted that APC approval confirms only the medicines related aspects of guidelines and that organisations needed to have systems in place to otherwise more generally approve and authorise the guidelines for use. APC agreed the need to ensure that the website makes this clear for those guidelines that are posted in its website.

Information leaflets for primary care for approval :

- Linaclotide for the treatment of moderate to severe Irritable Bowel Syndrome with constipation - approved
- Statement on prescribing intervals - approved

2014/54 Report from the Anti-microbial Chemotherapy subcommittee.

No report due.

2014/55 Documents previously circulated by e-mail

None

2014/56 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.

- TA312 - Multiple sclerosis (relapsing-remitting) alemtuzumab
- TA313 - Psoriatic arthritis (active) – ustekinumab
- TA315 - Canagliflozin in combination therapy for treating type 2 diabetes

2014/57 Northern (NHS) Treatment Advisory Group (N-TAG)

The following papers and recommendations were noted and the North of Tyne Formulary will be updated to reflect these decisions:

- NTAG draft minutes – 3/6/14
- NTAG Appeal process
- NTAG Terms of Reference - June 2014
- NTAG Decision Summary – Rivaroxaban for ACS – not recommended.
- NTAG Decision Summary – Dapoxetine for PE — not recommended.
- NTAG Decision Summary – High Dose Vitamins and Minerals for the prevention of Progression of AMD — not recommended.

2014/58 NHS England Specialised Services Approval

The following NHS England Specialised Service Approvals were noted:

- Specialised Commissioning drugs briefing, May 2014
- SSC1425 - National policy for targeted therapies for the treatment of pulmonary hypertension in adults - inclusion of Macitentan
- SSC1426 - Clinical Commissioning Policy: Disease Modifying Therapies for Patients with Multiple Sclerosis

- SSC1430 - Commissioning status of Oncotype DX®
- SSC1428 - Clinical Commissioning Policy: Levodopa/ Carbidopa (Duodopa®) Intestinal Gel for Advanced Parkinson's Disease

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

2014/59 Chair's action

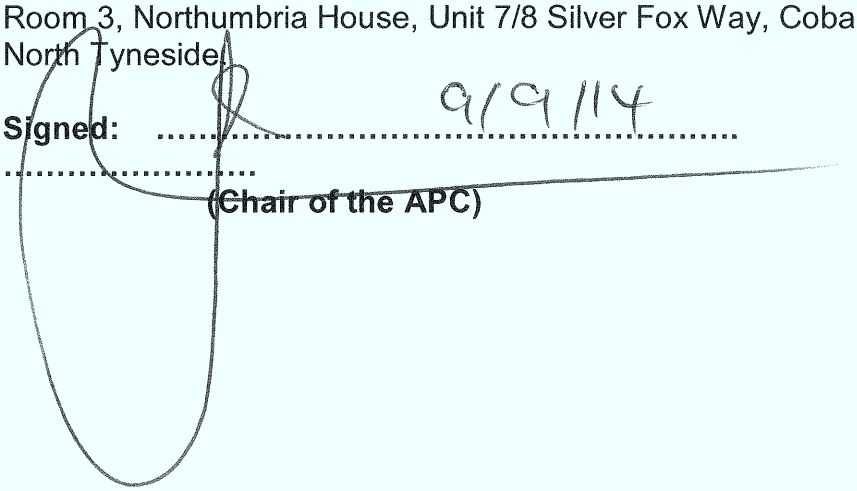
- C. diff assessment tool - approved
- Zero-Double – extension to previously approved range

2014/60 Any other business

HW raised a concern with regards to DMARD monitoring in primary care. Some practices appear to now be refusing to undertake this, with resulting inconvenience to patients. MG has been working with commissioners in Northumberland to address such issues. DC agreed to write to Steve Summers and Martin Wright to ask if there is anything the APC can do to facilitate the resolution of these problems in their respective areas.

2014/61 Date and time of next meeting

Tuesday 9th September 2014 at 12:30pm
Room 3, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside



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 8th July 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				
Dihydrocodeine	✓ R			Dihydrocodeine had been previously requested as a replacement for codeine in adult women post caesarean section who are breastfeeding. Further information on the appropriateness of this was requested. **Decision: Approved** Dihydrocodeine will be added to the formulary as a hospital only drug (red) for use in breast feeding mothers immediately post-delivery/c-section where adequate pain relief from has not been achieved using paracetamol and NSAIDs.
2) New Requests				
Dexmedetomidine 100mcg/ml solution for infusion (Dexdor®)			✓ R	Dexmedetomidine has been requested for use in adult intensive care unit patients for sedation. Dexmedetomidine is more expensive than midazolam and propofol but savings could be achieved due to the reduction in the need for mechanical ventilation. **Decision: deferred.** The request for dexmedetomidine was deferred until there was further clarification on advantages over midazolam and propofol and a more clearly defined position for use.
Certolizumab (Cimzia®) 200 mg prefilled syringe - Ankylosing spondylitis (AS)	✓ R			A previous application was refused but it was agreed this decision would be reassessed in light of the SMC decision once published. **Decision: Approved** Approved in adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Certolizumab (Cimzia®) 200 mg prefilled syringe – Psoriatic Arthritis	✓ R			A previous application was refused but it was agreed this decision would be reassessed in light of the SMC decision once published. **Decision: Approved** Approved in adults, in combination with methotrexate, for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate and as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Use should be restricted to patients whose disease has not responded to adequate trials of at least two standard DMARDs either individually or in combination.
3) New formulations & extensions to use				
Tocilizumab 162mg subcutaneous injection (RoActemra®)			✓	Tocilizumab subcutaneous injection (SC) has recently been licensed for rheumatoid arthritis. The IV formulation is NICE approved and on the formulary but the SC preparation has the advantage of being able to be self-administered, and therefore potentially delivered via Homecare arrangements. **Decision: Deferred** Clinically approved but an impact assessment for CCGs is needed prior to commencement of service.
Sodium picosulphate 5mg/5ml elixir (Dulcolax® Pico Liquid)	✓			Sodium picosulphate has been requested for use in paediatric patients with constipation. It will be given with movicol and is accepted as a well tolerated and reliable treatment option. **Decision: Approved** The request for sodium picosulphate elixir was approved as a second line agent in paediatric patients with constipation when movicol, lactulose and senna are ineffective as single agent therapy.
Emerade® 500 microgram auto-injector (Adrenaline 1:1000)	✓ B[S]			Emerade® 500 has been requested for adult patients in the emergency treatment of anaphylaxis. It is required for a small cohort of patients who are obese with a BMI of >40 or who have required more than one auto-injector (300mcg) previously to control symptoms. It was noted a recent MHRA review of adrenaline auto-injectors emphasised the importance of appropriate needle length for effective IM administration. **Decision: Approved** for the small cohort of patients indicated and for specialist initiation only.
Emerade® 500 microgram auto-injector (Adrenaline 1:1000)			✓	Emerade® 500 has been requested the NUTH community dental team for use in their anaphylaxis boxes instead of ampoules. This is on the grounds that dentists do not routinely give IM injections. Current UK RESUS guidelines, for health care professionals, recommend the use 500 micrograms of adrenaline for the treatment of anaphylaxis in adults. **Decision: Deferred** The request was deferred until further clarity is sought on the appropriateness of continued use of the ampoules.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Fosaprepitant 150mg injection (Ivemend®)	✓ R			Fosaprepitant has been requested for the treatment of chemotherapy induced nausea and vomiting. It is a prodrug of aprepitant and converted rapidly when given intravenously. It is recommended as a treatment option in the North of England Cancer Network Guidelines and is given as a single dose on day 1 of chemotherapy. It is cost neutral compared to aprepitant capsules. **Decision: Approved** The request for fosaprepitant injection was approved in line with North of England Cancer Network Guidelines.
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC1425- National policy for targeted therapies for the treatment of pulmonary hypertension in adults - inclusion of Macitentan	noted			The formulary will reflect the NHS England Specialised Services circular position.
SSC1426 -- Clinical Commissioning Policy: Disease Modifying Therapies for Patients with Multiple Sclerosis	noted			The formulary will reflect the NHS England Specialised Services circular position.
SSC1430 - Commissioning status of Oncotype DX®		noted		The formulary will reflect the NHS England Specialised Services circular position.
SSC1428 - Clinical Commissioning Policy: Levodopa/ Carbidopa (Duodopa®) Intestinal Gel for Advanced Parkinson's Disease	noted			The formulary will reflect the NHS England Specialised Services circular position.
5) Products considered by NICE				
TA312 - Multiple sclerosis (relapsing-remitting) alemtuzumab	noted			The formulary will reflect the NICE position
TA313- Psoriatic arthritis (active) – ustekinumab		noted		Negative appraisal. The formulary will reflect the NICE position
TA315 - Canagliflozin in combination therapy for treating type 2 diabetes	noted			The formulary will reflect the NICE position

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
NTAG Decision Summary – Rivaroxaban for ACS		noted		The Northern (NHS) Treatment Advisory Group does not recommend Rivaroxaban (Xarelto®▼) for acute coronary syndromes. The group was concerned with the quality of the clinical evidence (i.e. license based on one clinical trial with no active comparator and vital status missing for 8.4% of trial participants). The formulary will reflect the N-TAG position
NTAG Decision Summary – Dapoxetine for PE		noted		The Northern (NHS) Treatment Advisory Group does not recommend the use of dapoxetine for premature ejaculation. The group was concerned with the lack of any cost effectiveness and long term safety data. There were also concerns around the lack of consistency in diagnosis and the lack of any published active comparator trials. The formulary will reflect the N-TAG position
NTAG Decision Summary – High Dose Vitamins and Minerals for the prevention of Progression of AMD		noted		The Northern (NHS) Treatment Advisory Group does not recommend the use of high-dose vitamin and mineral supplements in the prevention of progression of AMD. The group was concerned with the quality of the clinical evidence (wide confidence interval) and the lack of any long term safety data with high dose supplementation. There is no data to support the use of vitamins and minerals in prevention of AMD i.e. in currently healthy patients with increased risk factors for AMD. The formulary will reflect the N-TAG position
7) Appeals against earlier decisions by the APC				
None				
8) Miscellaneous 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 felt there was not sufficient advantage over Movicol sachets to justify a 30% cost increase. **Decision: Refused**

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
levonorgestrel 1500 micrograms (Levonelle®)		✔		Data has been submitted to the EMA that suggests the efficacy of levonorgestrel 1500 micrograms is reduced in women weighing over 75kg. As per a previous NETAG decision levonorgestrel 1500 micrograms is the first choice for women up to 72 hours with ulipristal being advocated between 72 to 120 hours. The group noted the Faculty of Sexual and Reproductive Healthcare guidance (November 2013) that stated no further action was required. **Decision: Refused** The formulary will remain unchanged until a clear directive is received from regulators.