North of Tyne Area Prescribing Committee

Minutes of a meeting of the Area Prescribing Committee held on Tuesday 14th July 2015 at Northumbria House, Cobalt Business Park, North Tyneside

Present:

Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
Pat Bottrill	Lay Representative	
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
Neil Morris (NM)	Medical Director	NHS Newcastle Gateshead CCG
Helen Seymour (HS)	Senior Medicines Optimisation Pharmacist	NECS
Simon Thomas (STh) (Chair)	Consultant Clinical Pharmacologist	NUTH
Neil Watson(NW)	Clinical Director of Pharmacy and Medicines Management	NUTH

Apologies

Anne-Marie Bailey (AMB)	Senior Medicines Optimisation Pharmacist	NECS
David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Ian Campbell	Senior Pharmacist	NUTH
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Wendy Ross (WR)	GP and APC Representative	NHSNewcastle North & East CCG
Susan Turner (STu)	Medicines Optimisation Pharmacist	NECS
Steve Williamson(SW)	Consultant Pharmacist in Cancer Services	NHCT/NHSE

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

2015/52 Declarations of interest

No relevant declarations.

2015/53 Appeals against previous decisions

None

2015/54 Minutes and decision summary from the meeting held on Tuesday 12th May 2015

These were accepted as a true record.

2015/55 Matters arising not on the agenda.

Proposed merger of NoT APC and Gateshead medicines Management Committee (GMMC). NM outlined the discussions he has had with DCa, GMMC Chair and HS regarding a proposed merger of NoT APC and GMMC. The reason for this proposal was the merger of the three former CCGs in the Newcastle Gateshead CCG resulting in a single statutory commissioning organisation which necessitated a single local decision making mechanism for medicines. All involved in the discussions had agreed that there was a need to form a small task and finish group to discuss the arrangements for merging the two committees to include terms of reference, membership and the practicalities of merging formularies. NWa requested that the new committee considers how they assess new drugs ensuring that value for money to the NHS included patient outcomes, rather than acquisition cost alone. It was agreed that the key people to be included in the group are ML, DCa, STh, STu, NM, Martin Wright & Graham Syers. The APC agreed that the timescale for a new committee to be up and running was January 2016.

2015/39 – PB raised an issue regarding a report in the Daily Mail about PPIs causing a 16% increase in myocardial infarction. It was noted that this arose form a paper published in PLos One in June 2015. STh advised that he was not aware of advice provided by MHRA but will follow up. [Draft note – MHRA have not issued any advice as yet].

2015/56 Action Log

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

- Hyaluronic acid injections in osteoarthritis – comments have been received from specialists. Use is no longer supported. Remove from formulary.

2015/57 Report from the Formulary Sub-committee

Formulary version 5.9 is now available on the APC website.

Minutes and recommendations from the meeting held on 11th June 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:

- ML confirmed that levonorgestrel 13.5mg IUS was fitted in the same way as Mirena® IUS and no training issues were identified.
- ML confirmed that ivermectin 1% cream potentially prevented use of oral antibiotics and would be used where topical metronidazole had failed. The treatment pathway had been modified to reflect this.
- Ulipristal – a recent license change now allows up to 4 courses of treatment and a non-surgical license. It was agreed that the APC would approve the requested use for up to 2 treatment courses prior to surgery. Use for up to 4 courses or use in any non-surgical indication

would require a new application.

- Caverject® – supply problem. Viridal® Duo starter pack is now available to prescribe in primary care. It was agreed that new patients would be prescribed Viridal® Duo. ML agreed to contact the specialist nurses to identify which patients already receiving Caverject® would require re-training to use Viridal® Duo prior to switch.

2015/58 Report from the Medicines Guidelines and Use Group

- No report due

2015/59 NICE Technology Appraisals

The following Technology Appraisals were noted and the recommendations within them will be reflected in the formulary:

- TA339 Omalizumab for previously treated chronic spontaneous urticarial
- TA340 Ustekinumab for treating active psoriatic arthritis (rapid review of technology appraisal guidance 313)
- TA341 Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism
- TA342 Vedolizumab for treating moderately to severely active ulcerative colitis
- TA343 Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia
- TA344 Ofatumumab in combination with chlorambucil or bendamustine for untreated chronic lymphocytic leukaemia

2015/60 Northern (NHS) Treatment Advisory Group (N-TAG)

The following papers and recommendations were noted and will be reflected in the formulary :

- Draft minutes from meeting held on 2/6/15
- Treatment Appraisal - Decision Summary: Infliximab Biosimilars (Remsima® & Inflectra®). It was noted that NUTH will consider switching patients once data is available showing safety of biosimilar infliximab.
- Treatment Appraisal - Decision Summary :Teriparatide for the treatment of (bisphosphonate induced) atypical fractures.

2015/61 NHS England

The following NHS England communications were noted:

- SSC 1522 Eculizumab for treating atypical haemolytic uraemic syndrome
- SSC 1524 - Commissioning Policy Statement for treatment of chronic Hepatitis C in patients with cirrhosis
- SSC 1527: Nice TA 343 Obinutuzumab & Nice 344 Ofatumumab
- SSC 1528: Early Access to Medicines Scheme – Nivolumab for the treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults
- SSC1529 - NHS England Commissioning policy
- SSC1530 - Cancer Drugs Fund: Pemetrexed as maintenance treatment of stage IIIB/IV non-squamous non-small cell lung cancer after response to pemetrexed-containing first line therapy

2015/62 Chair's action

The following guidance has been approved:

- Diabetes Guideline

2015/63 Any other business

Mebeverine MR – HS requested that mebeverine MR should be added to the formulary as it offered cost savings over mebeverine IR. NICE CG61 (Irritable Bowel Syndrome) showed there was little difference between the two formulations. Agreed.

BMA – Duty of care to patients regarding test results. Agreed that MGUG should be asked to consider this advice when developing shared care guidelines.

2015/64 Date and time of next meeting

Tuesday 13th October
Room 4, Northumbria House, Unit 7/8 Silver Fox Way,
Cobalt Business Park,
North Tyneside.
The meeting will start at 12:30pm

Signed: ..... **Date:** 13/10/15
(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 14th July 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				
Levonorgestrel 13.5mg IUS (Jaydess®)	✓			Levonorgestrel 13.5mg IUS (Jaydess®) has been requested as a long acting reversible contraceptive (LARC) that differs from Mirena® in that the levonorgestrel dose is lower. It is licensed for nulliparous women but there is not sufficient evidence to support its first line use in this group. Jaydess® can only be used for 3 years compared to 5 years for Mirena® therefore it is marginally more expensive overall however the device is narrower, potentially making insertion easier. Due to the lower progesterone dose users are less likely to experience ovarian cysts. **Decision:** Levonorgestrel 13.5mg IUS (Jaydess®) was approved, as a green drug.
Ivermectin 1% cream (Soolantra®)	✓			Ivermectin 1% cream (Soolantra®) has been requested for the treatment of papulopustular rosacea. It has dual anti-inflammatory and anti-parasitic properties and has been compared with placebo and topical metronidazole. Some weaknesses were noted in the studies but compared with metronidazole it is marginally more effective in terms of reduction in lesion counts and it is well tolerated. Whilst the evidence of efficacy was not overwhelming it was felt that it could reduce the likelihood of some patients requiring systemic antibiotics, therefore the committee agreed it should be supported. **Decision:** The request for ivermectin 1% cream was approved as second line treatment for people who have failed topical metronidazole.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
3) **New Formulations & Extensions to Use**				
Ulipristal 5mg tablets (Esmya®)	✓ s see notes			Ulipristal 5mg tablets were added to the formulary in 2013, as a hospital only drug, for pre-op treatment of moderate to severe uterine fibroids in women of reproductive age. The product license was initially for 3 months treatment but that has subsequently been changed to allow a further 3 month course prior to surgery. A more recent license change now allows up to 4x 3month courses of treatment as well as a non-surgical indication. A request has been made to change the formulary status to specialist initiation to make it more convenient for patients to receive treatment from their GP (after the initial courseprovided by the specialist). Concerns were raised about patients being inadvertently being left on for long courses in primary care without appropriate specialist review. **Decision:** The request for the formulary status to be changed from red to "s" was approved but only for up to 2 treatment courses prior to surgery. Use for up to 4 courses, or use in any non-surgical indication, would require a new application. Clear communication between secondary and primary care should be provided to indicate this intended treatment duration.
Mebeverine MR	✓			Mebeverine MR will be added to the formulary as it currently offers cost savings over mebeverine IR. NICE CG61 (Irritable Bowel Syndrome) showed there was little difference between the two formulations.
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC 1522 Eculizumab for treating atypical haemolytic uraemic syndrome				NHS England position noted
SSC 1524 - Commissioning Policy Statement for treatment of chronic Hepatitis C in patients with cirrhosis				NHS England position noted
SSC 1527: Nice TA 343 Obinutuzumab & Nice 344 Ofatumumab				NHS England position noted

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
SSC 1528: Early Access to Medicines Scheme – Nivolumab for the treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults				NHS England position noted
SSC1529 - NHS England Commissioning policy				NHS England position noted
SSC1530 - Cancer Drugs Fund: Pemetrexed as maintenance treatment of stage IIIB/IV non-squamous non-small cell lung cancer after response to pemetrexed-containing first line therapy				NHS England position noted
5) Products considered by NICE				
TA339 Omalizumab for previously treated chronic spontaneous urticarial				The formulary will reflect the TAG.
TA340 Ustekinumab for treating active psoriatic arthritis (rapid review of technology appraisal guidance 313)				The formulary will reflect the TAG.
TA341 Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism				The formulary will reflect the TAG.
TA342 Vedolizumab for treating moderately to severely active ulcerative colitis				The formulary will reflect the TAG.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA343 Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia				The formulary will reflect the TAG.
TA344 Ofatumumab in combination with chlorambucil or bendamustine for untreated chronic lymphocytic leukaemia				The formulary will reflect the TAG.
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
Treatment Appraisal - Decision Summary: Infliximab Biosimilars (Remsima® & Inflectra®).				The formulary will reflect the N-TAG recommendation. It was noted that NUTH will consider switching existing patients once data is available showing the safety of switching from the originator brand to the biosimilar(s). Use in new patients is supported.
Treatment Appraisal - Decision Summary: Teriparatide for the treatment of (bisphosphonate induced) atypical fractures.				The formulary will reflect the N-TAG recommendation.
7) Appeals against earlier decisions by the APC				
None				
8) Miscellaneous decisions by the APC				
Viridal® Duo	The group was informed of a supply problem with Caverject® Dual Chamber injections. Alprostadil vials are still available, however the ancillary items are difficult to obtain and the increased risks from poor technique were noted. Viridal® Duo starter pack is now available to prescribe in primary care. It was agreed that new patients would therefore be prescribed Viridal® Duo. ML agreed to contact the specialist nurses to identify which patients already receiving Caverject® would require re-training to use Viridal® Duo prior to switch.			
Hyaluronic acid injection	Hyaluronic acid should be removed from the formulary as per NICE guidance.			
Plain emollient (Epimax®)	**Plain emollient (Epimax®)** A request has been received from North Tyneside CCG to use Epimax® cream as first line plain emollient in preference to generic options currently on the formulary as it is more cost effective. It was agreed that it could be added to the formulary in addition to current options allowing prescriber choice.			
Magnesium aspartate dihydrate sachets	Magnesium aspartate dihydrate sachets are now licensed for the treatment and prevention of magnesium deficiency and will therefore be added as 1st line agent over magnesium glycerophosphate.			