

**North of Tyne and Gateshead  
Area Prescribing Committee  
Minutes of a meeting held on  
Tuesday 12<sup>th</sup> April 2016  
at Northumbria House, Cobalt Business Park, North Tyneside**

**Present:**

Gary Armstrong	Team Leader	Pharmicus
Anne-Marie Bailey (AMB)	Senior Medicines Optimisation Pharmacist	NHS Newcastle Gateshead CCG
David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Helen Coundon	GP	NHS North Tyneside CCG
Sue Dickinson (SD)	Director of Pharmacy	RDTTC
Neil Gammack	Chief Pharmacist	GHFT
Matt Grove	Consultant Rheumatologist and Head of Service	NHCT
Tomal Karim		South Tyneside and Gateshead LPC
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Neil Morris (NM)	Medical Director	NHS Newcastle Gateshead 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
Steve Williamson(SW)	Consultant Pharmacist in Cancer Services	NHCT/NHSE

**Apologies**

Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
Pat Bottrill	Lay Representative	
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTW
Chris Jewitt	Prescribing lead	NHS Newcastle Gateshead CCG
Frank McAuley	Associate Medical Director	GHFT
Graham Syers	Prescribing Lead	NHS Northumberland CCG
Neil Watson(NW)	Clinical Director of Pharmacy and Medicines Management	NUTH
Martin Wright	Medical Director	NHS North Tyneside CCG
Andre Yeung	Specialist Pharmacy Advisor - Public Health	Newcastle City Council

GHFT	Gateshead Health NHS Foundation Trust
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
RDTTC	Regional Drugs and Therapeutics Centre

2016/19	<p><b>Resignations</b> Peter McEvedy has resigned from the committee. Graham Syers will join as the NHS Northumberland CCG representative. Dr McEvedy has been thanked personally by the chair for his valued contribution over the years. He will continue to represent Northumberland CCG at the Formulary sub-committee meetings.</p>
2016/20	<p><b>Declarations of interest</b> No relevant declarations were made.</p>
2016/21	<p><b>Appeals against previous decisions</b> None.</p>
2016/22	<p><b>Minutes and decision summary from previous meetings.</b> The following documents were accepted as a true record:</p> <ul style="list-style-type: none"> <li>• Decision summary from 12/1/16.</li> <li>• Minutes from 12/1/16</li> </ul>
2016/23	<p><b>Matters arising not on the agenda or Action Log.</b> None</p>
2016/24	<p><b>Action Log</b> The action log was reviewed and will be updated to reflect the following progress:</p> <ul style="list-style-type: none"> <li>• 2015/73 – Merger of NoT APC and Gateshead Medicines Management Committee (GMMC). MGUG has reviewed its Terms of Reference and membership. The formulary subcommittee will do so at their next meeting. Work on Formulary merging is underway and the new website is hoped to be in place by the end June.</li> <li>• 2016/07 – Idarucizumab - NUTH has shared their flow chart for use with Northumbria and Gateshead Trusts.</li> <li>• 2016/07 – Gentamicin intravesical installation – approval given. Audit is required to determine outcomes.</li> <li>• 2016/07 – Education event for new members in relation to local decision making. Scoping underway.</li> <li>• 2016/17 – Cancer drugs fund – SW responded to the national consultation on the future of the cancer drugs fund outlining concerns.</li> </ul>
2016/25	<p><b>Report from the Formulary Sub-committee</b> Formulary version 6.2 &amp; Traffic light list 01.16 are now available on the APC website.</p> <p><b>Minutes and recommendations from the North of Tyne &amp; Gateshead FSC meeting held on 3<sup>rd</sup> March:</b> 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 the decision summary. The following specific points were highlighted for further consideration:</p> <p><b>Dulaglutide 0.75mg – 1.5mg injection (Trulicity®)</b> Dulaglutide is a once weekly GLP-1 agonist. It has been requested for the treatment of type 2 diabetes. Studies showed better glycaemic control compared to insulin glargine with no increased hypoglycaemia risk. It was felt that the choice of GLP-1 agonists on the formulary should be determined as part of the review of the diabetes guidelines being undertaken by MGUG. If the review group feel they would like dulaglutide to be available to clinicians the application will be considered at that point.</p>

**Decision deferred:**

The request for dulaglutide injection was deferred pending the guideline review by MGUG.

**Aripiprazole 7.5mg/ml IM injection (Abilify®) for rapid tranquilisation**

Aripiprazole 7.5mg/ml IM injection has been requested for rapid tranquilisation (RT) in patients with acute psychosis. Aripiprazole is of similar efficacy to haloperidol and may be better tolerated due to less extrapyramidal symptoms. It is approved by the SMC but it is not recommended in a NICE clinical guideline. NICE recommend either IM haloperidol + promethazine or IM lorazepam. Continuing long term supply problems with lorazepam were noted. Use would be solely in NTW. An RT flowchart was presented and it was agreed this should be revised and presented at the next APC with clearer advice.

**Decision deferred:**

The request for aripiprazole IM injection was deferred until the revised flow chart outlining specific positioning was presented and approved by the APC

**Tadalafil 5mg once daily tablets (Cialis®)**

Once daily tadalafil has been requested as an alternative treatment for erectile dysfunction (ED) in patients with an inadequate response to maximum doses of on-demand PDE5 inhibitors. It is proposed that this would stop patients requiring more expensive or invasive preparations. There is evidence to support its use with 40% of patients responding. It was noted that the local ED guidelines are due for review.

**Decision deferred:**

The request for once daily tadalafil was deferred and will be re-considered if the forthcoming guideline development group wish this preparation to be added to the local ED guidelines as part of the review due in September 2016.

**2016/26****Report from the Medicines Guidelines and Use Group**

Minutes from the meeting on 2/3/16 were accepted.

Guidelines for approval:

- APC Guideline on Medicines that are Not Suitable for Generic Prescribing – approval to be given by chair's action at end April pending comments from Gateshead representatives.
- Primary care prescribing guidelines for specialist infant formulae – approval to be given by chair's action at end April pending comments from Gateshead representatives.
- Third Party Ordering – approval to be given by chair's action at end April pending comments from Gateshead representatives.
- Atomoxetine Shared Care Guideline for the treatment of ADHD in children and young people – Approved once Gateshead contact details are added.
- Dexamfetamine Shared Care Guideline for the treatment of ADHD in children and young people – Approved once Gateshead contact

	<p>details are added.</p> <ul style="list-style-type: none"> <li>• Dexamfetamine Shared Care Guideline for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults – Approved.</li> <li>• Methylphenidate Shared Care Guideline for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children and young people and for Giggle Incontinence in children aged 8 to 16 years – Approved once Gateshead contact details are added.</li> <li>• Methylphenidate Shared Care Guideline for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults – Approved.</li> <li>• Naltrexone Shared Care Guidance for use in the management of agitation and/or self-injurious behaviour in patients with autism or learning disabilities – Approved once Gateshead contact details are added.</li> </ul> <p>There has been a mapping exercise of existing North of Tyne and Gateshead guidelines with a view to rationalisation and consolidation moving forwards. Wherever possible guidelines will be developed in a way that they are not prescriptive in terms of local arrangements but rather they should be generic and as far as possible will be written in a way that can be applied across the localities.</p> <p><b>Shared Care Guidelines for immunosuppressive therapy</b></p> <p>NHSE has a national plan in place to repatriate the prescribing of immunosuppressant therapies for organ transplant patients from primary care to secondary care. This should have been completed by December 2015 but there has been slippage for some services. NHS England and NuTH still hope to complete some or at least have made good progress by 31/3/16. GPs have been advised to continue to provide immunosuppression until notified directly by the specialist team that a specific patient has been repatriated.</p> <p>The following was agreed:</p> <p><b>Immunosuppressive treatment following heart and lung transplants SCG</b> – No longer required, repatriation complete</p> <p><b>Immunosuppressive treatment following liver transplants SCG</b> – Remain in place, repatriation has not started yet</p> <p><b>Immunosuppressive treatment following paediatric renal transplantation SCG</b> – Remain in place – Process of repatriation is about to begin</p> <p><b>Immunosuppressive treatment following renal transplantation SCG</b> – Remain in place, no plans have been confirmed for repatriation of patients</p> <p>Specialist services will be asked to review and update current guidelines so that these can be reissues with revised expiry dates.</p>
2016/27	<p><b>Merger of North of Tyne APC and Gateshead MMC</b></p> <p>The revised Terms of Reference were agreed. These will be reviewed in 12 months.</p> <p>NM emphasised the importance of strong and consistent commissioner representation and contribution to the committee.</p>
2016/28	<p><b>Establishing Regional Medicines Optimisation Committees</b></p> <p>Keith Ridge, the Chief Pharmaceutical Officer for NHS England, has written to</p>

	<p>the four Regional Medical Directors outlining a desire to reduce duplication of effort in terms of evaluating new medicines and /or new indications for existing medicines that are not considered through the NICE TA process.</p> <p>A meeting to explore the best way forward is planned for w/c 18<sup>th</sup> April and David Campbell, as chair of the North of Tyne and Gateshead APC, has been invited. An update will be given at the July meeting.</p>
<p><b>2016/29</b></p>	<p><b>NICE Technology Appraisals</b></p> <p>The following Technology Appraisals were noted and the recommendations within them will be reflected in the formulary:</p> <ul style="list-style-type: none"> <li>• TA375 Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed</li> <li>• TA376 Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases</li> <li>• TA377 Enzalutamide for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated</li> <li>• TA378 Ramucirumab for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma previously treated with chemotherapy – Negative Appraisal</li> <li>• TA379 Nintedanib for treating idiopathic pulmonary fibrosis</li> <li>• TA380 Panobinostat for treating multiple myeloma after at least 2 previous treatments</li> <li>• TA381 Olaparib for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy</li> <li>• TA382 Eltrombopag for treating severe aplastic anaemia refractory to immunosuppressive therapy (terminated appraisal)</li> <li>• TA383 TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis</li> <li>• TA384 Nivolumab for treating advanced (unresectable or metastatic) melanoma</li> <li>• TA385 Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia</li> <li>• TA386 Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis</li> <li>• TA23 Updated Guidance on the use of temozolomide for the treatment of recurrent malignant glioma (brain cancer)</li> </ul>
<p><b>2016/30</b></p>	<p><b>Northern (NHS) Treatment Advisory Group (N-TAG )</b></p> <p>The recommendations from the meeting on 11/4/16 were not yet available to be shared with the committee and will therefore be presented in July.</p>

2016/31	<p><b>NHS England</b></p> <p>The following NHS England communications were noted:</p> <ul style="list-style-type: none"> <li>• SSC1602 Circular Provider Letter regarding 'NICE Technology Appraisal 370: Bortezomib for previously untreated mantle cell lymphoma'</li> <li>• SSC1606 regarding 'NICE Technology Appraisal 380: Panobinostat for treating multiple myeloma after at least 2 previous treatments'</li> <li>• SSC1607 regarding 'Cancer Drugs Fund and NICE Technology Appraisal 376: Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases'</li> <li>• SSC1608 'NICE Technology Appraisal 381: Olaparib for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum based chemotherapy'</li> <li>• SSC1609 'NICE Technology Appraisal 377: Enzalutamide for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated'</li> <li>• SSC1610 regarding 'NICE Technology Appraisal 379: Nintedanib for treating idiopathic pulmonary fibrosis'</li> <li>• SSC1611 - Early Access to Medicines Scheme - Treatment as monotherapy of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adult patients whose tumours express programmed death ligand-1 (PD-L1)</li> <li>• SSC1612 - Early Access to Medicines Scheme - Treatment as monotherapy of adult patients with advanced renal cell carcinoma after prior therapy</li> <li>• SSC1613 - A06/p/a Commissioning Policy: Dialysis Away from Base (DAFB) and Service Specification for DAFB</li> <li>• SSC1614 - HIV treatments update: February 2016</li> <li>• SSC1614 - HIV treatments update: February 2016 – Appendix 1</li> <li>• SSC1614 - HIV treatments update: February 2016 – appendix 2</li> <li>• SSC1616 - Individual Funding Requests</li> <li>• SSC1617 - NICE Technology Appraisal 384: Nivolumab for treating advanced (unresectable or metastatic) melanoma</li> <li>• SSC1618_Early Access to Medicines Scheme Pembrolizumab - Provider letter</li> </ul>
2016/32	<p><b>Chair's action</b></p> <p>The following two documents have been approved and posted on the APC website:</p> <ul style="list-style-type: none"> <li>• Updated oral anticoagulant comparison document</li> <li>• Updated Gluten free guidance for North Tyneside and Northumberland</li> </ul>
2016/33	<p><b>Any other business</b></p> <ol style="list-style-type: none"> <li>1. An update to the regional antimicrobial guidance has been developed. This will be shared with members and a 2 week period given for comments, at which points chair's approval will be given.</li> <li>2. The committee have been made aware of a Roche marketing campaign in relation to INR self-testing. The committee support NICE guidance in relation to anti-coagulation and monitoring and are aware of the potential impact on existing pathways of care if there is a sudden change in practice. The RDTC have agreed to undertake some cost/benefit analysis, and cost impact, in</li> </ol>

	relation to anti-coagulation, including self-testing.
<b>2016/34</b>	<b>Date and time of next meeting</b> Tuesday 12 <sup>th</sup> July 2016, 12.30pm Room 4, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside. The meeting will start at 12:30pm
	<b>Signed:</b> ..... <b>Date:</b> 12/7/16 (Chair of the APC)





## North of Tyne & Gateshead Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 12<sup>th</sup> April 2016**.

### 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	
<b>1) Requests deferred from previous meetings</b>				
<b>Gentamicin intravesical installation</b>	✓ <b>R</b>			<p>Gentamicin 80mg in 50mL sodium chloride 0.9% has been requested for use in patients with recurrent UTIs, refractory to all other treatments. Case reports suggest that intravesical administration could be an effective option for patients with recurrent UTIs who have exhausted all other options. NHFCT microbiologists supported its use but a decision in January was deferred until views from NUTH microbiologists were also received. They have now indicated their support of the application.</p> <p><b>Decision:</b> The request for gentamicin intravesical installation was approved. Audit will be required to determine clinical outcomes.</p>
<b>2) New Requests</b>				
<b>Ceftolozane/tazobactam 1.5g injection (Zerbaxa®)</b>	✓ <b>R</b>			<p>Ceftolozane/tazobactam 1g/500mg injection is a combination of a new cephalosporin and the beta lactamase inhibitor, tazobactam. It has been requested for use in multiply antibiotic resistant strains of enterobacteriaceae, pseudomonas and acinetobacters. It is non-inferior to levofloxacin for complicated UTIs, and it is non-inferior to meropenem for complicated intra-abdominal infections. It will have a role in carefully selected patients.</p> <p><b>Decision:</b> The request for Ceftolozane/tazobactam 1.5g injection was approved as a RED drug, following microbiology/infectious diseases physician advice.</p>
<b>Idarucizumab 2.5g injection</b>	✓ <b>R</b>			<p>Idarucizumab is a specific reversal agent for dabigatran. It has been request for adult patients when rapid reversal is required. It completely reverses the anticoagulant effect of dabigatran, is well tolerated and does not appear to have any adverse safety signals.</p> <p><b>Decision:</b> The request for idarucizumab 2.5g injection was approved as a RED drug.</p>

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
<b>Pitolisant 20mg tablets (Wakix<sup>®</sup>)</b>	✓ <b>R</b>			<p>Pitolisant is a histamine H3 receptor inverse agonist. It has been requested for patients with narcolepsy experiencing psychomotor side effects with stimulants such as modafinil and dexamfetamine. It currently has an orphan drug status but is going through full EMA submission. Studies show similar efficacy to modafinil without the usual stimulant adverse event profile.</p> <p><b>Decision:</b> The request for pitolisant was approved as a RED drug for specialist use. Feedback on patient response will be carried out and further evaluation conducted once licensed.</p>
<b>Dulaglutide 0.75mg – 1.5mg injection (Trulicity<sup>®</sup>)</b>			✓	<p>Dulaglutide is a once weekly GLP-1 agonist. It has been requested for the treatment of type 2 diabetes. Studies showed better glycaemic control compared to insulin glargine with no increased hypoglycaemia risk. It was felt that choice of GLP-1 agonists on the formulary should be determined as part of the review of the diabetes guidelines being undertaken by MGUG.</p> <p><b>Decision:</b> The request for dulaglutide injection was deferred pending the guideline review by MGUG.</p>
<b>3) New formulations &amp; extensions to use</b>				
<b>Aripiprazole 7.5mg/ml IM injection (Abilify<sup>®</sup>) for rapid tranquilisation</b>			✓ <b>R</b>	<p>Aripiprazole 7.5mg/ml IM injection has been requested for rapid tranquilisation (RT) in patients with acute psychosis. Aripiprazole is of similar efficacy to haloperidol and may be better tolerated due to less extrapyramidal symptoms. It is approved by the SMC but it is not recommended in a NICE clinical guideline. NICE recommend either IM haloperidol + promethazine or IM lorazepam. Continuing long term supply problems with lorazepam were noted. Use would be solely in NTW. An RT flowchart was presented and it was agreed this should be revised and presented at the next APC with clearer advice.</p> <p><b>Decision:</b> The request for aripiprazole IM injection was deferred until the revised flow chart outlining specific positioning was presented and approved by the APC</p>

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
<b>Azelastine hydrochloride 137mcg/fluticasone propionate 50mcg nasal spray (Dymista®)</b>		✓		<p>Dymista® has been requested as a third line agent for the treatment of moderate to severe seasonal rhinitis. This is a resubmission following its initial application 2 years ago when it was felt there was insufficient evidence to justify the extra cost. The price has subsequently been reduced by the manufacturer and is now the same price as the single ingredient azelastine spray. The benefit of the combination spray versus monotherapy with its constituent parts is modest; however it does have a more rapid onset of action. It was felt that rapid onset wasn't particularly relevant in this indication. It was also noted that there are significantly cheaper nasal corticosteroids available compared to fluticasone.</p> <p><b>Decision:</b> The request for Dymista was not approved on the grounds that the efficacy is modest compared to fluticasone and more cost effective nasal corticosteroid preparations are available.</p>
<b>Enoximone injection (oral) in adults with severe heart failure</b>	✓ <b>R</b>			<p>Orally administered enoximone injection has been requested for use in adults with severe heart failure to try and wean them from IV milrinone, as a bridge to transplant and to reduce the need for ventricular assist devices (VADs). VADs are associated with significant complications such as stroke. Its use allows discharge home whilst waiting for transplant. There is no robust evidence for its use however it is recognised that this is very niche area of practice where the evidence is sometimes hard to produce. It has previously been approved for use in paediatric patients.</p> <p><b>Decision:</b> The request for oral enoximone for adults with severe heart failure was approved as a RED drug</p>
<b>Lisdexamfetamine capsules (Elvanse®) in adults</b>	✓ <b>A</b>			<p>Lisdexamfetamine has been requested for the treatment of ADHD in adults. This is a new licensed indication. It is a schedule 2 controlled drug and subject to normal controlled drug regulations. It has been previously approved for use in children and adolescents. No other preparations are licensed for ADHD in adults. Lisdexamfetamine in trials improved symptoms and stimulated workplace performance compared to placebo.</p> <p><b>Decision:</b> The request for lisdexamfetamine was approved for the treatment of ADHD in adults as an AMBER drug.</p>
<b>Solifenacin/tamsulosin in (Vesomni®)</b>		✓		<p>Vesomni® has been requested for the treatment of lower urinary tract symptoms (LUTs) associated with benign prostatic hyperplasia in men not responding to an alpha blocker or antimuscarinic. It was noted that the supplied costing model used a comparison against the most expensive tamsulosin preparation therefore did not give an accurate reflection of potential savings. The application also suggests that first line use of solifenacin in these patients, which is not in line with the current formulary.</p> <p><b>Decision:</b> The request for Vesomni® was refused.</p>

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
<b>Tadalafil 5mg once daily tablets (Cialis®)</b>			✓	<p>Once daily tadalafil has been requested as an alternative treatment for erectile dysfunction (ED) in patients with an inadequate response to maximum doses of on-demand PDE5 inhibitors. It is proposed that this would stop patients requiring more expensive or invasive preparations. There is evidence to support its use with 40% of patients responding. It was noted that the local ED guidelines are due for review.</p> <p><b>Decision:</b> The request for once daily tadalafil was deferred and will be re-considered if the forthcoming guideline development group wish this preparation to be added to the local ED guidelines as part of the review due in September 2016.</p>
<b>Riluzole 5mg/ml oral suspension (Teglutik®)</b>	✓ R			<p>Riluzole 5mg/ml oral suspension has been requested for the treatment of amyotrophic lateral sclerosis. The solid formulation is currently in use within North of Tyne. This liquid formulation has recently come to market for patients with poor or no swallowing function. It was felt that there is a need for a liquid formulation. It was agreed that crushed tablets could continue to be used if appropriate risk assessment has been completed.</p> <p><b>Decision:</b> The request for riluzole 5mg/ml oral suspension was approved as a RED drug, for use when other preparations are not suitable (including crushing tablets)</p>
<b>Colecalciferol 2740iu/ml oral drops (Fultium®)</b>	✓ G			<p>Colecalciferol 2740iu/ml oral drops have been requested for use in children with defined deficiency syndromes and not for general supplementation. Its liquid formulation allows for dose variance and there is little or no associated taste or smell which will allow for greater patient compliance compared to Abidec®. It is cheaper than the current liquid formulation on the formulary.</p> <p><b>Decision:</b> The request for colecalciferol 2740iu/ml oral drops was approved. The colecalciferol 15,000iu/5ml oral solution should be removed from the formulary.</p>
<b>4) NHS England Specialised Services communications noted and endorsed by APC</b>				
<b>SSC1602 Circular Provider Letter regarding 'NICE Technology Appraisal 370: Bortezomib for previously untreated mantle cell lymphoma'</b>	✓ R			The formulary will reflect the policy outlined in this circular

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
<b>SSC1606 regarding 'NICE Technology Appraisal 380: Panobinostat for treating multiple myeloma after at least 2 previous treatments</b>	✓ <b>R</b>			The formulary will reflect the policy outlined in this circular
<b>SSC1607 regarding 'Cancer Drugs Fund and NICE Technology Appraisal 376: Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases</b>	✓ <b>R</b>			The formulary will reflect the policy outlined in this circular
<b>SSC1608 'NICE Technology Appraisal 381: Olaparib for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum based chemotherapy'</b>	✓ <b>R</b>			The formulary will reflect the policy outlined in this circular
<b>SSC1609 'NICE Technology Appraisal 377: Enzalutamide for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated'</b>	✓ <b>R</b>			The formulary will reflect the policy outlined in this circular
<b>SSC1610 regarding 'NICE Technology Appraisal 379: Nintedanib for treating idiopathic pulmonary fibrosis'</b>	✓ <b>R</b>			The formulary will reflect the policy outlined in this circular
<b>SSC1617 - NICE Technology Appraisal 384: Nivolumab for treating advanced (unresectable or metastatic) melanoma</b>	✓ <b>R</b>			The formulary will reflect the policy outlined in this circular
<b>5) Products considered by NICE</b>				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
<b>TA375 Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed</b>	✓ <b>R</b>			The formulary will reflect the position outlined in the TAG
<b>TA376 Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases</b>	✓ <b>R</b>			The formulary will reflect the position outlined in the TAG
<b>TA377 Enzalutamide for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated</b>	✓ <b>R</b>			The formulary will reflect the position outlined in the TAG
<b>TA378 Ramucirumab for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma previously treated with chemotherapy – Negative Appraisal</b>		✓		Negative appraisal
<b>TA379 Nintedanib for treating idiopathic pulmonary fibrosis</b>	✓ <b>R</b>			The formulary will reflect the position outlined in the TAG
<b>TA380 Panobinostat for treating multiple myeloma after at least 2 previous treatments</b>	✓ <b>R</b>			The formulary will reflect the position outlined in the TAG

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
<b>TA381 Olaparib for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum-based chemotherapy</b>	✓ <b>R</b>			The formulary will reflect the position outlined in the TAG
<b>TA382 Eltrombopag for treating severe aplastic anaemia refractory to immunosuppressive therapy (terminated appraisal)</b>		✓		Terminated Appraisal
<b>TA383 TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis</b>	✓ <b>R</b>			The formulary will reflect the position outlined in the TAG
<b>TA384 Nivolumab for treating advanced (unresectable or metastatic) melanoma</b>	✓ <b>R</b>			The formulary will reflect the position outlined in the TAG
<b>TA385 Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia</b>	✓			The formulary will reflect the position outlined in the TAG
<b>TA386 Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis</b>	✓ <b>R</b>			The formulary will reflect the position outlined in the TAG
<b>TA23 Updated Guidance on the use of temozolomide for the treatment of recurrent malignant glioma (brain cancer)</b>	✓ <b>R</b>			The formulary will reflect the position outlined in the TAG
<b>TA372 Apremilast for treating active psoriatic arthritis – negative appraisal</b>		✓		Negative appraisal
<b>TA373 Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis</b>	✓ <b>R</b>			The formulary will reflect the position outlined in the TAG

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
<b>6) Northern (NHS) Treatment Advisory Group (N-TAG )</b>				
None				
<b>7) Appeals against earlier decisions by the APC</b>				
None				
<b>8) Miscellaneous decisions by the APC</b>				
<b>Transdermal buprenorphine (NICE)</b>	See notes			<p>There is a currently a significant spend on non-formulary buprenorphine patches and CCGs wish to review the appropriateness of this. NICE recognise a particular defined role in palliative care. The lowest strength fentanyl patch (12 microgram) equates to approximately 30mg oral morphine daily however this can be too strong for some patients. In order to restrict use only the lower strength buprenorphine has been requested.</p> <p><b>Decision:</b> The lower strength buprenorphine patches should be added to the formulary for palliative care only and in cases where the 12 microgram fentanyl patch exceeds the patient's requirements. Patients should be transferred to fentanyl patches if possible once a higher daily opioid requirement has been reached.</p>
<b>Magnesium glycerophosphate 4mmol tablets.</b>	See notes			<p>Unlicensed magnesium glycerophosphate tablets (4mmol) are currently on the North of Tyne and Gateshead formularies. YourMag® is a food supplement that is produced to GMP standards in MHRA approved facilities. It does not attract additional dispensing fees and is available at a consistent price. Magnaphate® is a very similar preparation and is currently on the Gateshead primary care formulary.</p> <p><b>Decision:</b> It was agreed that Magnaphate® should be approved as the first choice magnesium glycerophosphate preparation on the formulary.</p>