North of Tyne and Gateshead Area Prescribing Committee Minutes of a meeting held on Tuesday 12th January 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
Catherine Baldridge	Medicines Management Lead Patient Safety – representing community nursing.	South Tyneside Foundation Trust
Arpita Bhattachayra (AB)	Consultant Community Paediatrician	NHCT
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	NHS North Tyneside CCG
Sue Dickinson (SD)	Director of Pharmacy	RDTC
Tim Donaldson (TD)	Trust Chief Pharmacist/Associate Director of Medicines Management	NTW
Matt Grove	Consultant Rheumatologist and Head of Service	NHCT
Chris Jewitt	Prescribing lead	NHS Newcastle Gateshead CCG
Tomal Karim		South Tyneside and Gateshead LPC
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Frank McAuley	Associate Medical Director	GHFT
Peter McEvedy (PMcE)	GP and Prescribing Lead	NHS Northumberland CCG
Neil Morris (NM)	Medical Director	NHS Newcastle Gateshead CCG
David Scott	Lead Pharmacy Technician	NUTH
Helen Seymour (HS)	Senior Medicines Optimisation Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Mark Thomas	Lead Clinical Pharmacist QE Gateshead	GHFT
Simon Thomas (STh) (Chair)	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
Martin Wright	Medical Director	NHS North Tyneside CCG
Andre Yeung	Specialist Pharmacy Advisor - Public Health	Newcastle City Council

Apologies

Alexander Dyker (AD)	Consultant Physician	NUTH
Neil Gammack	Chief Pharmacist	GHFT

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
RDTC	Regional Drugs and Therapeutics Centre

Mr Campbell welcomed members of both the North of Tyne APC and Gateshead MMC to the first meeting of the merged committee.

2016/01	**Resignations** Janet Kelly and Russell Buglass have both resigned from the North of Tyne committee. They have been thanked for their valued contribution.
2016/02	**Declarations of interest** No relevant declarations were made.
2016/03	**Appeals against previous decisions** None
2016/04	**Minutes and decision summary from previous meetings.** The following documents were accepted as a true record: • Decision summary from North of Tyne APC meeting 13/10/15. • Minutes from the North of Tyne APC meeting 13/10/15 • Minutes from Gateshead MMC meeting 11/11/15 • GMMC Decision Summary 11/11/15
2016/05	**Matters arising not on the agenda.** None
2016/06	**Action Log** The North of Tyne action log was reviewed and will be updated to reflect the following progress: • Phosphodiesterase type 5 (PDE5) inhibitor audit (Avanafil) – prescribing data shows that use of avanafil across the NoT area is <1% of total phosphodiesterase type 5 inhibitor costs therefore the committee were satisfied that the approval for use had not resulted in growth beyond forecast.
2016/07	**Report from the Formulary Sub-committee** Formulary version 6.1 is now available on the APC website. **Minutes and recommendations from the North of Tyne FSC meeting held on 19th November:** 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: **Nicardipine 10 mg/10 mL injection (Pre-eclampsia)** Concerns were raised regarding arterial BP monitoring outside of critical care areas due to the potential for large drops in blood pressure. Assurance has been given that there is appropriate HDU provision within maternity services.

Decision:
The request for IV nicardipine for pre-eclampsia was approved on the understanding that there is adequate provision of invasive blood pressure monitoring for women in the delivery suite.

Gentamicin intravesical installation in UTI

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 views from NUTH had yet to be sought. Audit would be required to determine clinical outcomes.

Decision deferred:
The request for gentamicin intravesical installation will be approved by chairs action once support from NUTH microbiologists is received.

Dihydrocodeine classification.

Following the MHRA alert, relating to codeine use in breastfeeding women, dihydrocodeine was added to the formulary as a red drug for use in post C-section pain. The red drug status has caused occasional difficulties for some patients who require longer courses than initially supplied in hospital. The committee agreed that GPs should be able to continue short term prescribing of dihydrocodeine post C-section without referral back to secondary care. Dihydrocodeine will remain a Red drug but an annotation will be made to the formulary to reflect this. Members requested that discharge notifications highlighted any complications that may contribute to short term ongoing use.

Idarucizumab

A specific dabigatran reversal agent, idarucizumab, has been licensed by Boehringer. A formulary application is expected. Individual Trusts may wish to stock idarucizumab in the interim following local risk assessment. NUTH has stock in place and a flow chart for use which they agreed to share with member organisations.

Gateshead MMC members will now join both MGUG and FSC.

Report from Formulary merging meeting 14/11/15

Minutes from a meeting held to discuss the practicalities of merging the two formularies were presented to the committee.

It was agreed that:

- Preparatory work to compare the formularies will be undertaken by the group and this will be completed by the end of January 2016.
- A chapter by chapter review will be undertaken to rationalise drug choice.
- The NoT APC formulary Blue classification will be replaced with Green Plus.

- A formal programme of ongoing review of the formulary chapters will be put in place.

Web Based Formulary: Proposal for Commissioners and member Trusts

As part of the initial discussion around merging the committees, it has been agreed in principle that the current word/PDF based formularies should be replaced with a specific, web-based, formulary software programme. A brief demonstration of formulary software was given.

Members agreed to progress discussions with Nottingham University Hospitals NHS Trust in relation to netFormulary. The website is hosted by the NUH IT Department on a dedicated server with full IT support. A specific website URL is provided (organisation-name.formulary.co.uk). All back-end database management work is provided by NUH which provides the following information and functions:

- Database with over 1000 categories, 30 main chapters and 4000 drugs. All new drugs and discontinued drugs would be added or removed as required.
- Accessible links to the most commonly used resource, i.e. BNF, BNFC, NICE and UKMI.
- Search function with a search box or the ability to select using the current BNF chapter structure.
- The ability to have an audit trail of activity and provision of website statistics.
- On-site training.
- Telephone and email support.
- Support importing existing formulary onto new website as required

A web based formulary has the distinct advantage that the content is primarily managed by the third party including building monographs for all new drugs. Additional benefits include:

- Instant updates to content.
- Free upgrades.
- 6 monthly full updates.
- Full chapter restructuring to mirror new BNF structure.
- All current documentation hosted on North of Tyne APC website and Newcastle Gateshead CCG website/Gateshead Health Foundation Trust websites could be hosted on netFormulary website with simple document uploads.
- Homepage can be designed specifically to meet the needs of the Trusts and CCG's.
- Multiple editors allowed content approvers can be limited accordingly.

The committee agreed that the advantages far outweighed the small costs associated and work will now begin to progress this with the intention that the first edition of the merged formulary should be in the new format.
BNF complete is currently used by NUTH but they supported the move towards this new version and will integrate existing processes with that.
Once the new website is in place there will be a need for a communications plan and this may also be an opportunity to run an education event for members in relation to local decision making. AMB agreed to explore the

	possibilities.
2016/08	**Report from the Medicines Guidelines and Use Group** Minutes from the meeting on 4/11/15 were accepted Guidelines for approval: • Updated Gluten free prescribing Guideline – this guideline currently relates to Northumberland and North Tyneside only. The committee expressed concern that it had not been possible to develop a guideline that covered the whole NoT APC area. Newcastle Gateshead CCG indicated that they are supportive of a move towards reduction in supply of gluten free products on prescription but need to finalise their consultation and communications process before implementing this change. There will therefore be two guidelines in place for a short period until this has happened. • Prescribing Guidelines for Stoma Accessories (Adult) – this updated guideline was approved. • Northern England Headache Guidelines – endorsed for use in this area. • Osteoporosis guidelines - approved. The chair of MGUG outlined some changes to the TORs and role of MGUG with regard to commissioning guidelines. It was agreed that the terms of reference should be changed to reflect that MGUG will offer advice and support in the development of guidelines. New criteria and principles for guideline development would give clarity to those wishing to develop guidelines as to what would be required to facilitate approval. It was recognised that MGUG is not the sole commissioner of guidelines but where they are to be considered by the group it should be clear that: • There should be a clearly defined need for local guidelines. • There is a need to adhere to NICE guidance and where NICE have already published any supplementary local information should only be produced to help provide clarity and ensure implementation. • They should be based on best available evidence • They should adhere to local formulary recommendations There may be some local pathway differences across the area but guidelines will give overarching principles that all members are in agreement with. **Re- audit of Tapentadol prescribing.** Tapentadol was approved by the NoT APC formulary in September 2013, after appeal, for use by chronic pain specialists in adults with severe pain who have been screened for a neuropathic element to their pain and are uncontrolled or experiencing GI side effects on existing therapy. At the appeal concerns were raised regarding the potential for widespread prescribing. Accordingly the North of Tyne Area Prescribing Committee requested that the Medicines Guidelines and Use Group monitor the use of Tapentadol. Prescribing was monitored in November 2014 and again towards the end of 2015. Prescribing has increased in all NoT CCGs, most notably Newcastle Gateshead CCG, however the number of items prescribed is still relatively low. The committee was reassured that prescribing rates are not escalating significantly and use is being restricted as initially outlined.
2016/09	**Merger of North of Tyne APC and Gateshead MMC** A draft Terms of Reference has been shared with members. Comments should

	be sent to the professional secretary. The NHS England planning guidance, and the increasing integration of the health and social care agendas, will need reflected. Membership and representation is still to be clarified but the chair of the committee indicated that it will not be necessary to have representation from all disciplines for each organisation, rather a representative who can liaise with colleagues across the geography of the committee. Once the Terms of Reference and representation are agreed members will be asked to put themselves or colleagues forward for the officer roles. A vote will be taken if there is more than one nomination for any particular post. In the meantime F McA and DC will continue to liaise in terms of chairing the meetings. The subgroups are also asked to review and update their Terms of Reference.
2016/10	**Clozapine and constipation - patient safety key card.** NTW shared an information card in relation to clozapine and constipation. Clozapine has been associated with varying degrees of impairment of intestinal peristalsis, ranging from constipation to intestinal obstruction, faecal impaction and paralytic ileus. On rare occasions these cases have been fatal. This educational tool is for member organisations to share with clinicians. It has already been disseminated to GP practices through the NECS MO newsletter.
2016/11	**Prison Pain Management Formulary** The Prison Healthcare Board (England), in association with the NHS England Health and Justice Clinical Reference Group, has published a recommended national pain management formulary for use in HM Prisons. The formulary supports clinicians in the management of acute or persistent pain and neuropathic pain for people taking account of the specific challenges of prescribing pain medicines in prisons. The publication of the prison formulary has prompted consideration of the purpose of the North of Tyne and Gateshead formularies. The committee agreed that the local formulary should be a resource to help clinicians understand first, second and third line choices and that the ongoing move to include more information relating to approvals in more specific circumstances/indications should continue.
2016/12	**Early Access to Medicines Scheme** The Early Access to Medicines Scheme was launched by the Medicines and Healthcare Regulatory Authority (MHRA) in April 2014. The scheme is intended to enable patient access to medicines for treatment of life threatening or seriously debilitating conditions where there is an unmet need. The committee considered: • Early Access to Medicines Scheme (eams)-letter-Oct15 • Sacubitril-valsartan EAMS public assessment report EAMS positioning was clarified. It was agreed that this does not remove the need for robust local decision making with regards to medicines. Once a product is licensed, clinicians can no longer use the product in line with the EAMS approval and therefore FSC or NICE approval will be needed before additional patients access any such product. Products that have been approved through the EAMS process will not be added to the formulary until one of these subsequent processes is complete and clinicians will not be supported in prescribing in line with EAMS once the licence is in place but before formulary inclusion has occurred. Concerns were expressed that use of free stock in advance of local decision making processes had the potential to create inequality of access and that

	there needed to be robust governance processes in place.
2016/13	**NICE Technology Appraisals** The following Technology Appraisals were noted and the recommendations within them will be reflected in the formulary: • TA357 Pembrolizumab for treating advanced melanoma after disease progression with ipilimumab • TA358 Tolvaptan for treating autosomal dominant polycystic kidney disease • TA359 Idelalisib for treating chronic lymphocytic leukaemia • TA360 Paclitaxel as albumin-bound nanoparticles in combination with gemcitabine for previously untreated metastatic pancreatic cancer • TA361 Simeprevir in combination with sofosbuvir for treating genotype 1 or 4 chronic hepatitis C (terminated appraisal) • TA362 Paclitaxel as albumin-bound nanoparticles with carboplatin for untreated non-small-cell lung cancer (terminated appraisal) • TA363 Ledipasvir–sofosbuvir for chronic hepatitis C • TA364 Daclatasvir for treating chronic hepatitis C • TA365 Ombitasvir–paritaprevir–ritonavir with or without dasabuvir for treating chronic hepatitis C • TA366 Pembrolizumab for advanced melanoma not previously treated with ipilimumab • TA367 Vortioxetine for treating major depressive episodes • TA368 Apremilast for treating moderate to severe plaque psoriasis • TA369 Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears • TA370 Bortezomib for previously untreated mantle cell lymphoma • TA371 Trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane • TA372 Apremilast for treating active psoriatic arthritis – negative appraisal • TA373 Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis • TA374 Erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior chemotherapy • HST2 Elosulfase alfa for treating mucopolysaccharidosis type IVa
2016/14	**Northern (NHS) Treatment Advisory Group (N-TAG)** The following recommendations were finalised by NTAG at their meeting on the 24th November and will be reflected in the formulary : • Alirocumab • Evolocumab • Insulin Glargine 300 units per ml (Toujeo®) • Insulin Glargine Biosimilar (Abasaglar®) The committee agreed that high dose insulins, as with all other insulins, should be prescribed by brand name.

2016/15	**NHS England** The following NHS England communications were noted: • SSC1542: Pembrolizumab post ipilimumab • SSC1543_Cancer Drugs Fund National CDF Cohort List • SSC1544: NICE Technology Appraisal 359 Idelalisib • SSC1545:Paediatric Uveitis Adalimumab • SSC1547:Nintedanib for non small cell lung cancer • SSC1549:NICE Technology Appraisal 339 Omalizumab for previously treated chronic spontaneous urticarial • SSC1550_NICE Technology Appraisal 366 Pembrolizumab for advanced melanoma not previously treated with ipilimumab • SSC1551: 'Early Access to Medicines Scheme – Osimertinib (AZD9291) • Clinical Commissioning Policy Ivacaftor for cystic fibrosis • Specialised Commissioning Drugs Briefing - December 2015 • NHS England home ventilation letter to CCGs Nov 2015 – Action: addition of water for infusion 1litre bag 'Viaflo®'
2016/16	**Chair's action** None
2016/17	**Any other business** NHS England and NICE have started a 12 week consultation to ask for views on the future direction of the Cancer Drugs Fund. SW is responding to this in his role within the cancer network .He will share his response with members.
2016/18	**Date and time of next meeting** Tuesday 12th April 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
	Signed: ..... **Date:** 12/4/16 **(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 12th January 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	
1) Requests deferred from previous meetings				
None				
2) New Requests				
Nicardipine 10 mg/10 mL injection (Aortic dissection)	✓ R			Intravenous (IV) nicardipine has been requested for use as a second line treatment for aortic dissection when first line agents have failed. This is now licensed in the UK. Evidence shows that in comparison to IV labetalol, nicardipine has a faster onset of action and is better tolerated. **Decision**: IV Nicardipine was approved as a second line agent for the treatment of aortic dissection.
Nicardipine 10 mg/10 mL injection (Pre-eclampsia)	✓ R			IV nicardipine has been requested as a second line treatment for pre-eclampsia. There is reasonable evidence of efficacy and safety in comparison to IV labetalol which is often used for this indication. Concerns were raised regarding arterial BP monitoring outside of critical care areas due to the potential for large drops in blood pressure but assurance has been given that there is appropriate HDU provision within maternity services. **Decision**: The request for IV nicardipine for pre-eclampsia was approved on the understanding that there is adequate provision of invasive blood pressure monitoring for women in the delivery suite.
Nicardipine 10 mg/10 mL injection (Acute stroke)			✓ R	IV nicardipine has been used in the US for acute stroke but no formal application has yet been made for local use. The committee agreed that a formal application outlining exact usage and monitoring requirements would be required before approval was given in this indication.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Whitmore cocktail - Hydrocortisone 100mg/Heparin 10,000units/ Bupivacaine 50mg in sodium chloride 0.9% (made up to 60ml). Bladder instillation	✓ R			Whitmore cocktail (hydrocortisone, heparin & bupivacaine bladder installation) has been requested for the treatment of interstitial cystitis/painful bladder syndrome (IC/PBS) in patients who have failed other treatments. There is no published evidence that examines the exact combination requested, although small uncontrolled studies indicate there is a role for similar combinations for treating IC/PBS. It was recognised that IC/PBS is an extremely unpleasant condition with limited therapeutic options. It was agreed that audit should take place following 12 months to ascertain definitive clinical outcomes. **Decision:** The request for Whitmore cocktail was approved subject to an audit of clinical outcomes being reported back to FSC in 12 months. Cystistat© and Ialuril© will remain first line treatments
3) New formulations & extensions to use				
Ondansetron 4mg and 8mg oro-dispersible film (Setofilm®)	✓ R			Ondansetron oro-dispersible film (Setofilm®) has been requested for the treatment of post-operative nausea and vomiting (PONV). This is for use in patients who are nil by mouth and who do not require IV access for other treatments, or who have difficult IV access. **Decision:** Ondansetron oro-dispersible formulations - approved for PONV only, when IV access is not available, as a Red drug. The cheapest available formulation should be used.
Prednisolone Dompé 1mg/ml oral solution	✓ G			Prednisolone Dompé oral solution has been requested as a cheaper alternative to the currently available 5mg soluble tablets. It is not licensed for doses above 30mg. There is not support from secondary care paediatricians at NUTH to remove the soluble tablets from the formulary. **Decision:** The request for Prednisolone Dompé oral solution was approved in addition to prednisolone 5mg soluble tablets. The lowest cost agent should be used where clinically appropriate.
Dinoprostone 10mg pessary (Propess®)	✓ R			Dinoprostone 10mg pessaries have been requested as an alternative preparation for the induction of labour. This preparation is less intrusive, allowing quicker mobilisation following labour. In the long-term it has the potential to allow for out-patient induction in low-risk patients. It is included in the most recent NICE guidance for the induction of labour in addition to the current formulary option, dinoprostone 3mg tablets. **Decision:** The request for dinoprostone 10mg pessaries was approved.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Medroxyprogesterone acetate 104mg/0.65mL injection (Sayana Press®)	✓ G			Medroxyprogesterone acetate 104mg/0.65mL injection has been requested as an alternative to Depo-Provera®. It is bio-equivalent and is licensed for self-administration by subcutaneous injection, thus there is potential to save nurse / clinic time. **Decision:** The request for medroxyprogesterone acetate 104mg/0.65mL injection (Sayana Press®) was approved, in addition to Depo-Provera®
Gentamicin intravesical installation			✓ R	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 views from NUTH had yet to be sought. Audit would be required to determine clinical outcomes. **Decision deferred:** The request for gentamicin intravesical installation will be approved by chairs action once support from NUTH microbiologists is received.
Captopril 1mg/1ml suspension	✓			Captopril 1mg/1mL suspension is currently on formulary as an unlicensed special but a new licensed preparation is now available. **Decision:** The new licensed captopril suspension will be included as the first line liquid formulary choice. As with any liquid alternative to oral dosage forms, awareness is needed in relation to increased cost and appropriate use.
Clobazam 1mg/1mL and 2mg/1ml suspension	✓			Clobazam 1mg/1mL and 2mg/1mL suspensions are currently on the formulary as unlicensed specials but licensed preparations are now available. **Decision:** The new licensed preparations will be included as first line liquid formulary choice. As with any liquid alternative to oral dosage forms, awareness is needed in relation to increased cost and appropriate use.
Fluoxetine 20mg dispersible tablets	✓			Fluoxetine 20mg dispersible tablets will be added to the formulary as a first choice for patients unable to use the capsules as these are currently cheaper than fluoxetine liquid.
Midodrine 2.5mg and 5mg tablets	✓S			Currently only 5mg tablets are listed on formulary but 2.5mg are also now available as a licensed product. Both strengths will now be listed on formulary and the unlicensed status removed. The formulary annotation will be changed to “for specialist initiation in treating symptomatic hypotension that has not responded to conventional therapies”.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC1542: Pembrolizumab post ipilimumab	✓ R			The formulary will reflect the policy outlined in this circular
SSC1544: NICE Technology Appraisal 359 Idelalisib	✓ R			The formulary will reflect the policy outlined in this circular
SSC1545:Paediatric Uveitis Adalimumab	✓ R			The formulary will reflect the policy outlined in this circular
SSC1547:Nintedanib for non small cell lung cancer	✓ R			The formulary will reflect the policy outlined in this circular
SSC1549:NICE Technology Appraisal 339 Omalizumab for previously treated chronic spontaneous urticarial	✓ R			The formulary will reflect the policy outlined in this circular
SSC1550_NICE Technology Appraisal 366 Pembrolizumab for advanced melanoma not previously treated with ipilimumab	✓ R			The formulary will reflect the policy outlined in this circular
Clinical Commissioning Policy Ivacaftor for cystic fibrosis	✓ R			The formulary will reflect the policy outlined in this circular
5) Products considered by NICE				
TA357 Pembrolizumab for treating advanced melanoma after disease progression with ipilimumab	✓ R			The formulary will reflect the position outlined in the TAG
TA358 Tolvaptan for treating autosomal dominant polycystic kidney disease	✓ R			The formulary will reflect the position outlined in the TAG

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA359 Idelalisib for treating chronic lymphocytic leukaemia	✓ R			The formulary will reflect the position outlined in the TAG
TA360 Paclitaxel as albumin-bound nanoparticles in combination with gemcitabine for previously untreated metastatic pancreatic cancer		✓		Negative appraisal
TA361 Simeprevir in combination with sofosbuvir for treating genotype 1 or 4 chronic hepatitis C				terminated appraisal
TA362 Paclitaxel as albumin-bound nanoparticles with carboplatin for untreated non-small-cell lung cancer				terminated appraisal
TA363 Ledipasvir–sofosbuvir for chronic hepatitis C	✓ R			The formulary will reflect the position outlined in the TAG
TA364 Daclatasvir for treating chronic hepatitis C	✓ R			The formulary will reflect the position outlined in the TAG
TA365 Ombitasvir–paritaprevir–ritonavir with or without dasabuvir for treating chronic hepatitis C	✓ R			The formulary will reflect the position outlined in the TAG
TA366 Pembrolizumab for advanced melanoma not previously treated with ipilimumab	✓ R			The formulary will reflect the position outlined in the TAG
TA367 Vortioxetine for treating major depressive episodes	✓			The formulary will reflect the position outlined in the TAG
TA368 Apremilast for treating moderate to severe plaque psoriasis		✓		Negative appraisal

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA369 Ciclosporin for treating dry eye disease that has not improved despite treatment with artificial tears	✓s			The formulary will be amended to include the licensed product as the first line option. Use will be initiated by specialists with ongoing prescribing in primary care providing the appropriate provision is in place for review in line with licence - no later than 6 months
TA370 Bortezomib for previously untreated mantle cell lymphoma	✓ R			The formulary will reflect the position outlined in the TAG
TA371 Trastuzumab emtansine for treating HER2-positive, unresectable locally advanced or metastatic breast cancer after treatment with trastuzumab and a taxane	✓ R			The formulary will reflect the position outlined in the TAG
TA372 Apremilast for treating active psoriatic arthritis – negative appraisal		✓		Negative appraisal
TA373 Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis	✓ R			The formulary will reflect the position outlined in the TAG
TA374 Erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed after prior chemotherapy	✓ R			The formulary will reflect the position outlined in the TAG
HST2 Elosulfase alfa for treating mucopolysaccharidosis type IVa	✓ R			The formulary will reflect the position outlined in the TAG
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
Alirocumab (Praluent®▼, Sanofi) for the treatment of primary hypercholesterolaemia and mixed dyslipidaemia.		✓		The Northern (NHS) Treatment Advisory Group does not recommend the use of alirocumab for the above indication.
Evolocumab (Repatha®▼, Amgen) for the treatment of primary hypercholesterolaemia and mixed dyslipidaemia.		✓		The Northern (NHS) Treatment Advisory Group does not recommend the use of evolocumab for the above indication.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Toujeo®▼ (Sanofi) Insulin Glargine 300 units/ml for the treatment of type 1 or type 2 diabetes mellitus.	✔			The Northern (NHS) Treatment Advisory Group recommends the use of Toujeo® insulin glargine as an option for use in adults who are eligible for treatment with insulin glargine as per NICE guidance (NG17, 2015). The formulary will reflect this position.
Abasaglar®▼ Insulin Glargine Biosimilar 100 units/ml for the treatment of type 1 or type 2 diabetes mellitus.	✔			The Northern (NHS) Treatment Advisory Group recommends the use of Abasaglar© insulin glargine biosimilar as a first line option for use in adults who are eligible for treatment with insulin glargine as per NICE guidance (NG17, 2015). The formulary will reflect this position.
7) Appeals against earlier decisions by the APC				
None				
8) Miscellaneous decisions by the APC				
Dihydrocodeine	See notes			Following the MHRA codeine alert in breastfeeding women dihydrocodeine was added to the formulary as a red drug for use in post C-section pain. The red drug status has caused occasional difficulties for some patients who required longer courses than initially supplied in hospital. The committee agreed that GPs should be able to continue short term prescribing of dihydrocodeine post C-section rather than sending the patient back to hospital to receive it. Dihydrocodeine will remain a Red drug but an annotation will be made to the formulary to reflect this.
Idarucizumab				A specific dabigatran reversal agent, idarucizumab, has been licensed by Boehringer. A formulary application is expected. Individual Trusts may wish to stock idarucizumab in the interim following local risk assessment.