North of Tyne and Gateshead Area Prescribing Committee
Minutes of a meeting held on Tuesday 10th October 2017 at Northumbria House, Cobalt Business Park, North Tyneside

Present:

Pat Bottrill	Lay Representative	
David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Optimisation	NHCT
Ian Campbell		NUTH
Sarah Chandler (SC)	Formulary Pharmacist	NHCT
Helen Coundon	Prescribing Lead	North Tyneside CCG
Sue Dickinson (SD)	Director of Pharmacy	RDTC
Tim Donaldson	Trust Chief Pharmacist/Associate Director of Medicines Management	NTW
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
Frank McAulay (FM)	Associate Medical Director	GHFT
Neil Morris (NM)	Medical Director	Newcastle Gateshead CCG
Helen Seymour (HS)	Senior Medicines Optimisation Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Graham Syers	Prescribing Lead	Northumberland CCG
Simon Thomas (STh)	Consultant Clinical Pharmacologist	NUTH
Sarah Tulip	Medicines Optimisation Pharmacist	Newcastle Gateshead CCG
Susan Turner	Medicines Optimisation Pharmacist	NECS
Steve Williamson (SW)	Consultant Pharmacist in Cancer Services	NHCT/NHSE
Martin Wright	Medical Director	North Tyneside CCG

Apologies

Neil Watson	Clinical Director of Pharmacy and Medicines Management	NUTH
Sue White	Medicines Optimisation Pharmacist	Gateshead Public Health

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

2017/50	**Declarations of interest** None. Annual notifications are now due.
2017/51	**Appeals against previous decisions** **Insulin Degludec** Dr Nicola Leech attended to present the grounds of the appeal. Supplementary information including the following was presented to the committee o Birmingham, Sandwell, Solihull and environs Area Prescribing Committee (BSSE APC) approval o Tresiba Budget impact modelling o JAMA paper 2017 – Lane et al. o Degludec audit write up **Decision** Use of Degludec U100 was approved for use in patients with Type 1 diabetes, for the initiation in specialist care only, in line with the indications below: • Nocturnal/Severe Hypoglycaemia (with or without hypoglycaemic unawareness) in patients who would otherwise progress to insulin pump treatment as per NICE TA 151. OR • Recurrent DKA episodes despite good compliance and who would otherwise progress to insulin pump therapy. An audit of initiation and continuation/discontinuation criteria as outlined in the Birmingham Sandwell Amber Drug review form should be completed and submitted back to the committee in 1 year. **Safinamide** Dr Naomi Warren attended to present the grounds of the appeal. o Original application o Refusal notification o Email of support from Richard Athey at QE The committee was minded to approve the use of safinamide in restricted groups of patients but asked for further information that clearly defines • the criteria by which initiation would be defined and • the criteria by which an objective assessment of improvement, which included cessation criteria, would be measured The following information was provided subsequent to the meeting and deemed satisfactory: Safinamide will be used in mid-late stage PD in patients on levodopa who are having fluctuations affecting their quality of life. All patients will have had to have tried rasagiline first but if ineffective or side effects then we will stop and switch to safinamide. If the patient does not see an improvement in their motor fluctuations that is providing an improvement in their movements and quality of life at their next review (which is usually 6 months), or if they are suffering adverse effects then safinamide will be stopped. Decision – Approved.

2017/52	**Minutes and decision summary from previous meeting.** The following documents were accepted as a true record: • Decision summary from 11/07/17. • Minutes from 11/07/17.
2017/53	**Matters arising not on the agenda or Action Log.** None.
2017/54	**Action Log** The action log was reviewed and will be updated to reflect the following: • 2016/26: Shared Care Guidelines for immunosuppressive therapy following paediatric renal transplantation. ML to chase. • 2016/56: Rituximab –a review of previous approvals is being undertaken to ensure legacy commissioning decisions are in line with national policy statements. The outcome of the review will be presented at the November FSC. • 2016/58: Osteoporosis guidelines - Next meeting scheduled for 19/10/17 • 2017/41: Guanfacine- Agenda item 2017/55 – remove from action log • 2017/41: Lidocaine Patches consultation– Agenda item 2017/55 – remove from action log
2017/55	**Report from the Formulary Sub-committee** The formulary website is available at North of Tyne and Gateshead Area Prescribing Committee Formulary. **Minutes and recommendations from the North of Tyne & Gateshead FSC meeting held on 07/09/17:** The above minutes and recommendations were received by the committee. The summary of recommendations made in relation to new product requests is listed in the decision summary. The following specific points were highlighted for further consideration: **Sufentanil 15microgram sublingual tablets (Zalviso®)** Sublingual sufentanil, delivered by the Zalviso® patient controlled analgesia device (PCA), has been requested for post-operative patients who've had a total knee replacement. IV PCA restricts patient mobility and compliance with physiotherapy in comparison to oral analgesia, whereas oral analgesia is time consuming for nursing staff. The device has a number of security features. Efficacy and tolerability are similar to IV morphine PCA although this should be interpreted with caution due to the open label nature of the study. A small evaluation at Gateshead FT indicated the system saved 80% of nursing time compared to oral therapy and 30% of the time compared to IV PCA. The CD accountable offer (Chief Pharmacist) at Gateshead FT was consulted for his view regarding the risks of diversion and disposal and confirmed he had no significant concerns. The company have provided details relating to disposal which NG agreed to share with members. The team supporting the NHS England CDAO are also happy with arrangements. The evaluation by Gateshead FT on patient outcomes, duration of stay and the impact on nursing time should be extended to 100 patients and results reported back to the FSC. **Decision: Approved** The request for Zalviso® was only approved for patients who have had total knee replacement as part of enhanced recovery programme. This is subject to the evaluation being extended to include 100 patients and including impact on length of stay.

Guanfacine
The request had been previously deferred until suitable arrangements for transitioning patients to adult services are in place and clarified within shared care guidance. These arrangements have now been clarified.

Decision: Approved
Guanfacine hydrochloride has been requested as a 3rd line treatment of ADHD in children and adolescents when 1st line stimulants and atomoxetine are contraindicated or ineffective. The request for guanfacine was approved for children and adolescents as an Amber drug. Guanfacine can also be prescribed by GPs in adult patients who are receiving it when they transition into the adult service.

Aviptadil 25microgram/ Phentolamine 2mg solution for injection (Invicorp®)
Aviptadil/phentolamine has been requested as a 3rd line option for the treatment of erectile dysfunction. It is of similar efficacy to alprostadil, although the study was poorly designed and may have overestimated efficacy. It causes less injection pain compared to alprostadil. Its anticipated place in therapy would be as an alternative to intracaversonal alprostadil in patients who have failed PDE5 inhibitors.

Decision: Approved
The request for aviptadil/phentolamine (Invicorp®) was approved, subject to further clarification of the treatment sequence.

Glycopyrronium Bromide 2mg/5ml oral solution (Sialanar®)
Glycopyrronium bromide 2mg/5ml has been requested for the treatment of severe sialorrhoea in children and adolescents with chronic neurological disorders. It has recently been licensed by EMA for this indication. The use of Sialanar® in children was considered preferable compared to off-label use of the Colonis® preparation due to availability of risk management materials.

Decision: The request for glycopyrronium bromide 2mg/5ml (Sialanar®) was approved for the treatment of severe sialorrhoea in children and adolescents with chronic neurological disorders. The applicant will be asked to provide further guidance on where in the treatment pathway it will sit.

Post meeting information has been provided that confirms use will be in line with the NICE guidance for the management Cerebral Palsy (NG62), in particular in the management of drooling in children.

IV lidocaine – pain management

Decision: Approved
The request for IV lidocaine was approved for post-operative pain management subject to local protocols being in place, and a review of adverse events being submitted to the FSC after 1 year. Further clarification is required on the types of surgery it will be used for.

Post meeting clarification:
IV lidocaine is opioid sparing and a good alternative when a patient can't have epidural analgesia for whatever reason .The indications are likely to include:

	1. Complex Spinal surgeries 2. Complex laparotomies 3. Complex Gynae and urological surgery 4. Lap and Open cholecystectomies 5. Complex Upper GI surgeries 6. Complex ICU patients **Lidocaine Patches** Lidocaine 5% plasters are licensed for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN) in adults. The current North of Tyne and Gateshead APC formulary position is that lidocaine 5% plasters are approved for use in the treatment of chronic neuropathic pain on the advice of pain specialists only, subject to an appropriate trial of efficacy in each individual patient. Given the (a) lack of evidence to support their use (b) high relative cost and (c) national moves to restrict their usage the committee was minded to remove Lidocaine 5% plasters from the local formulary but before making a final decision, consulted with clinicians on the following options: 1. Lidocaine 5% plasters should be completely removed from the formulary. 2. Lidocaine 5% plasters should be restricted to specialist pain clinic initiation for its licensed indication of PHN only. 3. The current position of lidocaine 5% plasters on the formulary should remain unchanged, i.e. used in the treatment of chronic neuropathic pain on the advice of pain specialists only, subject to an appropriate trial of efficacy. **Decision:** The committee noted the ongoing national consultation in terms of products of limited clinical value, and that PHN is often used as a clinical trial model for neuropathic pain. The decision was therefore made to endorse an interim position whereby lidocaine patches are approved for specialist initiation in neuropathic pain. Ongoing review of efficacy should be undertaken by the prescribing clinician. Member organisations will ensure their clinicians are aware of, and adhere to, this restricted approval. The position will be reviewed pending the outcome of the national consultation **Alimemazine** There has been a significant price increase in the price of alimemazine. The committee was asked to consider if it still represents a cost-effective choice of sedating antihistamine and if there are any specific indications where use is still justified. Alimemazine is used for enteral sedation in NUTH paediatric ITUs and very occasionally for sedation in other paediatric patients. Following discussions within NUTH around its use in non ITU patients it has been suggested that it should be used only in cases where promethazine has failed. **Decision:** Alimemazine will be retained on formulary as a red drug for enteral sedation in NUTH paediatric ITUs and very occasionally for sedation in other paediatric patients. Existing patients can continue to be prescribed it in primary care until there is an opportunity to review their treatment.
2017/56	**Report from the Medicines Guidelines and Use Group**

Minutes from the meeting on 13/09/17 were accepted.
The following points were noted:

Clinical Guidelines for approval:

- Menopause – approval was made by chairs action following the July APC meeting. A minor amendment to clarify advice relating to the availability of some products on prescription had been made and was presented directly to the APC - approved.
- Blood Glucose Monitoring – minor update – approved.
- Hypertension Guideline – 2017 update – approved.
- Kidney Guidelines – minor update – approved.
- Diabetes stepped approach – approved.

Shared Care Guideline(s) for approval:

- Guanfacine Shared Care Guidance for the Management of ADHD in Children and Young People – approved.
- Ketamine in Palliative Care – update – approved.
- Shared Care Guidelines for the Use of Dronedarone – update – approved.

Information leaflets for approval:

- Acetylcholinesterase inhibitors: information for primary care – update – approved.
- Memantine: information for primary care – update – approved.

Guideline(s)and information sheets for removal:

MGUG agreed that the following guidance, currently on the APC website, is no longer needed:

Linaclotide Information Sheet – Jul 2014
Rosuvastatin – Jan 2014
Epilepsy GL NOT – Jan 2014 - NICE and SIGN are enough
Midazolam Buccal (Buccolam) – Information for Primary Care – Jul 2014
Midazolam Buccal (Epistatus) – Information for Primary Care – Jul 2014
Pramipexole – Nov 2013
Rasagiline – Nov 2013
Retigabine – Jan 2014
Ropinirole – Nov 2014 (Updated)
Rotigotine Patches – Nov 2013
Tapentadol Information Sheet (Final) – May 14
Triptorelin (Decapeptyl SR) Use in the Management of Precocious Puberty – Jan 2014
Chorionic Gonadotrophin – Nov 2013
Tacrolimus Ointment – Sep 2012
Exenatide – Sep 2012
Humulin R U500 insulin – Jan 2014

Newcastle Gateshead CCG indicated following the MGUG meeting that their Gluten free guidance is no longer required as they are adopting the regional policy. Work will be undertaken to consider if the Northumberland/North Tyneside Guidance is now suitable for adoption across the area.

	APC Guideline on Prescribing PPIs – Mar 2015 – ML to ask one of their pharmacists to review. Lidocaine Plasters – Nov 2013 – To be reviewed following the outcome of the recent local consultation on use.
2017/57	**Regional commissioning policy regarding the treatment of Age-related Wet Macular Degeneration** Email correspondence had been circulated prior to the meeting which provided the context for discussion. IC informed the group that NUTH will not follow the CCG policy on the use of bevacizumab for AMD until the legal position has been clarified and new NICE clinical guidelines have been issued; NUTH will continue to use NICE approved options. CCG members expressed concern that there was no opportunity for further discussion to understand why this decision had been reached. However, it was acknowledged that, as the APC had not been invited to review the policy, any further discussion should instead take place between commissioners and relevant provider organisation(s) directly.
2017/58	**Role of CCG prescribing forum** GS, chair of the regional prescribing forum, gave an update on the work it is progressing. He agreed to share the terms of reference with members. DC commented on the increasing complexity of various reference groups, decision making bodies and forums across the region, all with a potential impact on prescribing, and agreed to map out the current situation.
2017/59	**RMOC** No update
2017/60	**Optimising anticoagulation pathways in Newcastle** Joanne Smithson, Digital Health Programme Lead at the AHSN for the North East and North Cumbria updated the committee on a joint AHSN/NGCCG/ NUTHFT project aimed at Optimising the AF Pathway for patients.
2017/61	**Previously circulated** • NHS England consultation on items of limited value https://www.engage.england.nhs.uk/consultation/items-routinely-prescribed/ • Details of the CCG forum regional self-care project
2017/62	**NICE Technology Appraisals** The following Technology Appraisals were noted and the recommendations within them will be reflected in the formulary: • HST6 Asfotase alfa for treating paediatric-onset hypophosphatasia • TA452 Ibrutinib for untreated chronic lymphocytic leukaemia without a 17p deletion or TP53 mutation (terminated appraisal) • TA453 Bortezomib for treating multiple myeloma after second or subsequent relapse (terminated appraisal) • TA454 Daratumumab with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal) • TA455 Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people • TA456 Ustekinumab for moderately to severely active Crohn's disease after previous treatment • TA457 Carfilzomib for previously treated multiple myeloma • TA458 Trastuzumab emtansine for treating HER2-positive advanced

	breast cancer after trastuzumab and a taxane • TA459 Collagenase clostridium histolyticum for treating Dupuytren's contracture • TA460 Adalimumab and dexamethasone for treating non-infectious uveitis • TA461 Roflumilast for treating chronic obstructive pulmonary disease • TA462 Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma • TA463 Cabozantinib for previously treated advanced renal cell carcinoma • TA464 Bisphosphonates for treating osteoporosis • TA465 Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma • TA466 Baricitinib for moderate to severe rheumatoid arthritis • TA467 Holoclar for treating limbal stem cell deficiency after eye burns • TA468 Methylnaltrexone bromide for treating opioid-induced constipation (terminated appraisal) • TA469 Idelalisib with ofatumumab for treating chronic lymphocytic leukaemia (terminated appraisal) • TA470 Ofatumumab with chemotherapy for treating chronic lymphocytic leukaemia (terminated appraisal) • TA471 Eluxadoline for treating irritable bowel syndrome with diarrhea • TA472 Obinutuzumab with bendamustine for treating follicular lymphoma refractory to rituximab • TA473 Eluxadoline for treating irritable bowel syndrome with diarrhoea • TA474 Sorafenib for treating advanced hepatocellular carcinoma • TA475 Dimethyl fumarate for treating moderate to severe plaque psoriasis • TA476 Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic pancreatic cancer • TA477 Autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee • TA478 Brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma • TA479 Reslizumab for treating severe eosinophilic asthma
2017/63	**Northern (NHS) Treatment Advisory Group (N-TAG)** The following recommendations were finalised by NTAG at their meeting on the 29/09/17and are now available on the website http://ntag.nhs.uk/html/latest_news.html : • Paliperidone long acting injection (Xeplion®) and Paliperidone 3 monthly injection (Trevicta®) Janssen-Cilag for schizophrenia. • Updated guidance on the use of long-acting antipsychotic injections in the North of England. • Liraglutide (Saxenda®) for treatment of obesity – negative appraisal. • Northern Treatment Advisory Group: 3rd Annual Report, June 2017
2017/64	**NHS England** The following NHS England communications were noted and will be reflected in the formulary: • SSC1745 - NICE Technology Appraisal 441: Daclizumab for treating relapsing–remitting multiple sclerosis

- SSC1745 – EMA letter Daclizumab for treating relapsing–remitting multiple sclerosis liver safety
- SSC1746 (Updated) - NICE Technology Appraisal 443: Obeticholic acid for treating primary biliary cholangitis
- SSC1760 -National Framework Agreement for Human Immunoglobulins
- SSC1762 - NICE Technology Appraisal Final Appraisal Determination: Cabozantinib for the treatment of renal cell carcinoma [TA10075]
- SSC1763 - Technology Appraisal 448: Etelcalcetide for treating secondary hyperparathyroidism
- SSC1764: Clarification statement re National Framework Agreement for Immunoglobulins SSC1760
- SSC1765 - Update on the HIV Switch Initiatives (Anti-Retroviral Therapies). Supplementary information to SSC1632, SSC1650 & SSC1681 (National Anti-Retroviral Therapy Commissioning for Value 2016-2018)
- SSC1766 - Anti-retroviral drugs for treatment of young people (aged 6-12 years of age) with diagnosed HIV: Reimbursement of Dolutegravir in paediatric patients under existing Dolutegravir Clinical Commissioning Policy (Ref: NHS England: B06/P/a)
- SSC1767 - NICE Technology Appraisal Final Appraisal Determination: Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) with gemcitabine for untreated metastatic pancreatic cancer
- SSC1768 - Urgent Clinical Commissioning Policy Statement (170018/P): Nusinersen for genetically confirmed Spinal Muscular Atrophy (SMA) type 1 for eligible patients under the Biogen Access Scheme
- SSC1769 - NICE Technology Appraisal 462: Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma
- SSC1771 - Abiraterone for hormone-sensitive metastatic prostate cancer
- SSC1772 - NICE Technology Appraisal Final Appraisal Determination: sorafenib for the treatment of advanced hepatocellular carcinoma only for people with Child-Pugh grade A
- SSC1773 - NICE Technology Appraisal Final Appraisal Determination: Cetuximab for the treatment of metastatic and/or recurrent squamous cell carcinoma of the head and neck (oral cavity only)
- SSC1774 - NICE Technology Appraisal Final Appraisal Determination: Obinutuzumab with bendamustine for treating rituximab-refractory follicular lymphoma
- SSC 1775 - NICE Highly Specialised Technology HST6: Asfotase alfa for treating paediatric-onset hypophosphatasia
- SSC1776 - Biosimilar Rituximab
- SSC1777 - Commissioning of Palivizumab (To Reduce the Risk of RSV in High Risk Infants) for the 2017 Vaccination Season
- SSC1779 - NICE Technology Appraisal Final Appraisal Determination: Brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma
- SSC1780 - NICE Technology Appraisal 460: Adalimumab for treating non-infectious uveitis
- SSC1781 - Technology Appraisal 467: Holoclar for treating limbal stem cell deficiency after eye burns
- SSC1782 - Early Access to Medicines Scheme – Alectinib as monotherapy for the first line treatment of adult patients with anaplastic

	lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) • SSC1783 - NICE Technology Appraisal 473: Cetuximab for the treatment of metastatic and/or recurrent squamous cell carcinoma of the head and neck (review of TA172) • SSC1784 - NHS England Policy for Urgent Cases • SSC1785 - NICE Highly Specialised Technology 5: Eliglustat for treating type 1 Gaucher disease • SSC1787 Nivolumab for previously treated non-small-cell lung cancer - Provider Letter • SSC1788 - NICE Technology Appraisal 446: Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma • SSC1789 - NICE Technology Appraisal 450: Blinatumomab for previously treated Philadelphia-chromosome-negative acute lymphoblastic leukaemia • SSC1790 - NICE Technology Appraisal 451: Ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia • SSC1791 - NICE Technology Appraisal 449: Everolimus and sunitinib for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease • SSC1792 - Anti-retroviral drugs for treatment of HIV: Reimbursement of Raltegravir Once Daily Formulation
2017/65	**Chair's action** • Blood glucose monitoring guidance – July 2017 update – approved.
2017/66	**Any other business** i/v bisphosphonates have previously been considered as adjunctive treatment in breast cancer. SW clarified that the administration is not classified as chemotherapy and therefore falls to CCGs to fund. HS reiterated the previous position that CCG contract managers need trusts to present details on how the additional activity will impact on services.
2017/67	**Date and time of next meeting(s)** Tuesday 8th January 12.30pm Room 4, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.
	Signed: ..... **Date:** 8/1/18 **(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 10th October 2017.**

Classification of products:

R = 'RED' drugs for hospital use only
A = 'AMBER' drugs suitable for use under Shared Care arrangements
G+ = 'GREEN PLUS – Drugs normally recommended or initiated by hospital specialist, but where the provision of an information leaflet may be appropriate to facilitate continuing treatment by GPs. Many of these information sheets are in the process of development.
G = 'GREEN' – Drugs where initiation by GPs is appropriate.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
Guanfacine 1mg, 2mg, 3mg and 4mg prolonged release tablets (Intuniv®)	✓ A			Guanfacine has been requested as 3rd line treatment of ADHD in children and adolescents when 1st line stimulants and atomoxetine are contraindicated or ineffective. It appears to be more effective than atomoxetine however it has significant side effects such as sedation, syncope, hypotension and bradycardia. **Decision:** The request for guanfacine was approved for children and adolescents as an Amber drug. Guanfacine can also be prescribed by GPs in adult patients who are receiving it when they transition into the adult service.
Ceftriaxone injection	✓ G+			Ceftriaxone will be re-classified as a green plus drug to allow for use within primary care (i.e. care homes) to treat patients with conditions such as UTI and pneumonia, at risk of sepsis, only in line with local guidance. **Decision:** Approved for use as a green plus drug for use in primary care subject to local guidelines with microbiology input.
2) New Requests				
Dulaglutide 0.75mg and 1.5mg pre-filled syringe (Trulicity®)	✓ G+			Dulaglatide is a once weekly GLP-1 receptor agonist that has been requested as a replacement for once weekly exenatide. This is on the grounds that the administration is easier, dose titration is not required and they are cost equivalent. Dulaglatide is non-inferior to liraglutide and superior to daily exenatide **Decision:** The request for dulaglutide was approved. Once weeky exenatide will be removed from the formulary.Existing once weekly exenatide patients can continue to be prescribed this in primary care until it is reviewed by a specialist.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Aviptadil 25microgram/ Phentolamine 2mg solution for injection (Invicorp®)	✓			Aviptadil/phentolamine has been requested as a 3rd line option for the treatment of erectile dysfunction. It is of similar efficacy to alprostadil, although the study was poorly designed and may have overestimated efficacy. It causes less injection pain compared to alprostadil. Its anticipated place in therapy would be as an alternative to intracaversonal alprostadil in patients who have failed PDE5 inhibitors. **Decision:** The request for aviptadil/phentolamine (Invicorp®) was approved, subject to further clarification of the treatment sequence.
Sufentanil 15microgram sublingual tablets (Zalviso®)	✓			Sublingual sufentanil, delivered by the Zalviso® patient controlled analgesia device (PCA), has been requested for post-operative patients who've had a total knee replacement. IV PCA restricts patient mobility and compliance with physiotherapy in comparison to oral analgesia, whereas oral analgesia is time consuming for nursing staff. The device has a number of security features. Efficacy and tolerability are similar to IV morphine PCA although this should be interpreted with caution due to the open label nature of the study. A small evaluation at Gateshead FT indicated the system saved 80% of nursing time compared to oral therapy and 30% of the time compared to IV PCA. The CD accountable offer (Chief Pharmacist) at Gateshead FT was consulted for his view regarding the risks of diversion and disposal and confirmed he had no significant concerns. The team supporting the NHS England CDAO are also happy with arrangements. The evaluation by Gateshead should be extended to 100 patients and results reported back to the FSC. **Decision:** The request for Zalviso® was only approved for patients who have had total knee replacement as part of enhanced recovery programme. This is subject to the evaluation being extended to include 100 patients and including impact on length of stay.
3) New formulations & extensions to use				
Calcipotriol 50 microgram/ betamethasone 0.5mg/g cutaneous spray (Enstilar®)	✓			Enstilar® is a once daily fixed dose foam product for the treatment of plaque psoriasis. It will be used in preference to Dovobet® ointment, however Dovobet® should remain on formulary for the purpose of patient choice. A head to head study suggests that Enstilar® is more efficacious than Dovobet® ointment after 4 weeks of treatment. Due to lack of other foam preparations it was felt that the Enstilar® could be more difficult to step down from and this will need to be managed. **Decision:** The request for Enstilar® was approved.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Glycopyrronium Bromide 2mg/5ml oral solution (Sialanar®)	✓			Glycopyrronium bromide 2mg/5ml has been requested for the treatment of severe sialorrhoea in children and adolescents with chronic neurological disorders. It has recently been licensed by EMA for this indication. The use of Sialanar® in children was considered preferable compared to off-label use of the Colonis preparation due to availability of risk management materials. **Decision:** The request for glycopyrronium bromide 2mg/5ml (Sialanar®) was approved for the treatment of severe sialorrhoea in children and adolescents with chronic neurological disorders. The applicant will provide further guidance on where in the treatment pathway it will sit.
IV lidocaine – pain management	✓			IV lidocaine for post-operative pain management has been used in the Freeman Hospital and RVI for a number of years. Its use, and lack of formulary approval, has recently been highlighted due to the submission of an internal protocol. Two Cochrane reviews suggest some benefit. There is the potential of significant patient harm due to dosing errors. The draft protocol contains information on dosing, method of administration as well as rigorous monitoring procedures. **Decision:** The request for IV lidocaine was approved for post-operative pain management subject to local protocols being in place, and a review of adverse events being submitted to the FSC after 1 year. Further clarification is required on the types of surgery it will be used for.
Farmigea ocular lubricants	✓			Currently the formulary contains a range of preservative-free ocular lubricants which are available in a multi-drop bottles, single use vials and ointments. Farmigea offer a similar range which could potentially lead to savings in primary care. The unit dose vials are re-sealable allowing them to be used up to 4 times per day instead of single use. **Decision:** The brands of the ocular lubricants will be removed from the formulary to allow for the most cost-effective product to be promoted.

4) NHS England Specialised Services communications noted and endorsed by APC

SSC1745 - NICE Technology Appraisal 441: Daclizumab for treating relapsing–remitting multiple sclerosis	The formulary will reflect the SSC
SSC1745 – EMA letter Daclizumab for treating relapsing–remitting multiple sclerosis liver safety	The formulary will reflect the SSC
SSC1746 (Updated) - NICE Technology Appraisal 443: Obeticholic acid for treating primary biliary cholangitis	The formulary will reflect the SSC
SSC1760 -National Framework Agreement for Human Immunoglobulins	The formulary will reflect the SSC
SSC1762 - NICE Technology Appraisal Final Appraisal Determination: Cabozantinib for the treatment of renal cell carcinoma [TA10075]	The formulary will reflect the SSC
SSC1763 - Technology Appraisal 448: Etelcalcetide for treating secondary hyperparathyroidism	The formulary will reflect the SSC
SSC1764: Clarification statement re National Framework Agreement for Immunoglobulins SSC1760	The formulary will reflect the SSC

Product	Decision Approved | Refused | Deferred	Comments/notes
SSC1765 - Update on the HIV Switch Initiatives (Anti-Retroviral Therapies). Supplementary information to SSC1632, SSC1650 & SSC1681 (National Anti-Retroviral Therapy Commissioning for Value 2016-2018)		The formulary will reflect the SSC
SSC1766 - Anti-retroviral drugs for treatment of young people (aged 6-12 years of age) with diagnosed HIV: Reimbursement of Dolutegravir in paediatric patients under existing Dolutegravir Clinical Commissioning Policy (Ref: NHS England: B06/P/a)		The formulary will reflect the SSC
SSC1767 - NICE Technology Appraisal Final Appraisal Determination: Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) with gemcitabine for untreated metastatic pancreatic cancer		The formulary will reflect the SSC
SSC1768 - Urgent Clinical Commissioning Policy Statement (170018/P): Nusinersen for genetically confirmed Spinal Muscular Atrophy (SMA) type 1 for eligible patients under the Biogen Access Scheme		The formulary will reflect the SSC
SSC1769 - NICE Technology Appraisal 462: Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma		The formulary will reflect the SSC
SSC1771 - Abiraterone for hormone-sensitive metastatic prostate cancer		The formulary will reflect the SSC
SSC1772 - NICE Technology Appraisal Final Appraisal Determination: sorafenib for the treatment of advanced hepatocellular carcinoma only for people with Child-Pugh grade A		The formulary will reflect the SSC
SSC1773 - NICE Technology Appraisal Final Appraisal Determination: Cetuximab for the treatment of metastatic and/or recurrent squamous cell carcinoma of the head and neck (oral cavity only)		The formulary will reflect the SSC
SSC1774 - NICE Technology Appraisal Final Appraisal Determination: Obinutuzumab with bendamustine for treating rituximab-refractory follicular lymphoma		The formulary will reflect the SSC
SSC 1775 - NICE Highly Specialised Technology HST6: Asfotase alfa for treating paediatric-onset hypophosphatasia		The formulary will reflect the SSC
SSC1776 - Biosimilar Rituximab		The formulary will reflect the SSC
SSC1777 - Commissioning of Palivizumab (To Reduce the Risk of RSV in High Risk Infants) for the 2017 Vaccination Season		The formulary will reflect the SSC
SSC1779 - NICE Technology Appraisal Final Appraisal Determination: Brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma		The formulary will reflect the SSC
SSC1780 - NICE Technology Appraisal 460: Adalimumab for treating non-infectious uveitis		The formulary will reflect the SSC
SSC1781 - Technology Appraisal 467: Holoclar for treating limbal stem cell deficiency after eye burns		The formulary will reflect the SSC
SSC1782 - Early Access to Medicines Scheme – Alectinib as monotherapy for the first line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)		The formulary will reflect the SSC
SSC1783 - NICE Technology Appraisal 473: Cetuximab for the treatment of metastatic and/or recurrent squamous cell carcinoma of the head and neck (review of TA172)		The formulary will reflect the SSC
SSC1784 - NHS England Policy for Urgent Cases		The formulary will reflect the SSC
SSC1785 - NICE Highly Specialised Technology 5: Eliglustat for treating type 1 Gaucher disease		The formulary will reflect the SSC
SSC1787 Nivolumab for previously treated non-small-cell lung cancer - Provider Letter		The formulary will reflect the SSC
SSC1788 - NICE Technology Appraisal 446: Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma		The formulary will reflect the SSC

Product	Decision Approved | Refused | Deferred	Comments/notes
SSC1789 - NICE Technology Appraisal 450: Blinatumomab for previously treated Philadelphia-chromosome-negative acute lymphoblastic leukaemia		The formulary will reflect the SSC
SSC1790 - NICE Technology Appraisal 451: Ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia		The formulary will reflect the SSC
SSC1791 - NICE Technology Appraisal 449: Everolimus and sunitinib for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease		The formulary will reflect the SSC
SSC1792 - Anti-retroviral drugs for treatment of HIV: Reimbursement of Raltegravir Once Daily Formulation		The formulary will reflect the SSC
5) Products considered by NICE		
HST6 Asfotase alfa for treating paediatric-onset hypophosphatasia		The formulary will reflect the NICE Guidance
TA452 Ibrutinib for untreated chronic lymphocytic leukaemia without a 17p deletion or TP53 mutation (terminated appraisal)		
TA453 Bortezomib for treating multiple myeloma after second or subsequent relapse (terminated appraisal)		
TA454 Daratumumab with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal)		
TA455 Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people		The formulary will reflect the NICE Guidance
TA456 Ustekinumab for moderately to severely active Crohn's disease after previous treatment		The formulary will reflect the NICE Guidance
TA457 Carfilzomib for previously treated multiple myeloma		The formulary will reflect the NICE Guidance
TA458 Trastuzumab emtansine for treating HER2-positive advanced breast cancer after trastuzumab and a taxane		The formulary will reflect the NICE Guidance
TA459 Collagenase clostridium histolyticum for treating Dupuytren's contracture		The formulary will reflect the NICE Guidance
TA460 Adalimumab and dexamethasone for treating non-infectious uveitis		The formulary will reflect the NICE Guidance
TA461 Roflumilast for treating chronic obstructive pulmonary disease		The formulary will reflect the NICE Guidance
TA462 Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma		The formulary will reflect the NICE Guidance
TA463 Cabozantinib for previously treated advanced renal cell carcinoma		The formulary will reflect the NICE Guidance
TA464 Bisphosphonates for treating osteoporosis		The formulary will reflect the NICE Guidance
TA465 Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma		The formulary will reflect the NICE Guidance

Product	Decision Approved	Refused	Deferred	Comments/notes
TA466 Baricitinib for moderate to severe rheumatoid arthritis				The formulary will reflect the NICE Guidance
TA467 Holoclar for treating limbal stem cell deficiency after eye burns				The formulary will reflect the NICE Guidance
TA468 Methylnaltrexone bromide for treating opioid-induced constipation (terminated appraisal)				
TA469 Idelalisib with ofatumumab for treating chronic lymphocytic leukaemia (terminated appraisal)				
TA470 Ofatumumab with chemotherapy for treating chronic lymphocytic leukaemia (terminated appraisal)				
TA471 Eluxadoline for treating irritable bowel syndrome with diarrhea				The formulary will reflect the NICE Guidance
TA472 Obinutuzumab with bendamustine for treating follicular lymphoma refractory to rituximab				The formulary will reflect the NICE Guidance
TA473 Cetuximab for treating recurrent or metastatic squamous cell cancer of the head and neck				The formulary will reflect the NICE Guidance
TA474 Sorafenib for treating advanced hepatocellular carcinoma				The formulary will reflect the NICE Guidance
TA475 Dimethyl fumarate for treating moderate to severe plaque psoriasis				The formulary will reflect the NICE Guidance
TA476 Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic pancreatic cancer				The formulary will reflect the NICE Guidance
TA477 Autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee				The formulary will reflect the NICE Guidance
TA478 Brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma				The formulary will reflect the NICE Guidance
TA479 Reslizumab for treating severe eosinophilic asthma				The formulary will reflect the NICE Guidance
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
Paliperidone long acting injection (Xeplion®) and Paliperidone 3 monthly injection (Trevicta®) Janssen-Cilag for schizophrenia.	✓			Approved in line with the NTAG guidance and the updated guidance on the use of long-acting antipsychotic injections in the North of England.
Liraglutide (Saxenda®) for treatment of obesity – negative appraisal.		✓		

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
7) Appeals against earlier decisions by the APC				
Safinamide			✓	**Decision - deferred** The committee was minded to approve the use of safinamide in restricted groups of patients but have asked for further information that clearly defines • the criteria by which initiation would be defined and • the criteria by which an objective assessment of improvement, which included cessation criteria, would be measured
Insulin Degludec	✓ G3			**Decision** Use of Degludec U100 was approved for use in patients with Type 1 diabetes, for the initiation in specialist care only, in line with the indications below: • Nocturnal/Severe Hypoglycaemia (with or without hypoglycaemic unawareness) in patients who would otherwise progress to insulin pump treatment as per NICE TA 151. OR • Recurrent DKA episodes despite good compliance and who would otherwise progress to insulin pump therapy. An audit of initiation and continuation/discontinuation criteria as outlined in the Birmingham Sandwell Amber Drug review form should be completed and submitted back to the committee in 1 year.
8) Miscellaneous decisions by the APC				
Lidocaine patch consultation	Given the lack of evidence to support their use, the high relative cost and national moves to restrict their use, the North of Tyne and Gateshead Area Prescribing Committee are minded to remove lidocaine 5% plasters from the formulary. Views were sought from prescribers before a decision was made: • A total of 24 responses were received, seven from primary care and seventeen from secondary care. • Option 1 - Only one responders was in favour i.e. total removal from formulary (Newcastle & Gateshead CCG) • Option 2 - Seven responders were in favour of option 2 (i.e. restricted to pain specialists for Post Herpetic Neuralgia only). Two from primary care and five from secondary care. • Option 3 – Sixteen responders were in favour of option 3 (i.e. formulary position remains unchanged). Four from primary care and twelve from secondary care. **Decision:** The committee noted the ongoing national consultation in terms of products of limited clinical value, and that PHN is often used as a clinical trial model for neuropathic pain. The decision was therefore made to endorse an interim position whereby lidocaine patches are approved for specialist initiation in neuropathic pain. Ongoing review of efficacy should be undertaken by the prescribing clinician. Member organisations will ensure their clinicians are aware of, and adhere to, this restricted approval. The position will be reviewed pending the outcome of the national consultation.			

Product	Decision Approved | Refused | Deferred	Comments/notes
Alimemazine		There has been a significant price increase in the price of alimemazine. The committee was asked to consider if it still represents a cost-effective choice of sedating antihistamine and if there are any specific indications where use is still justified. **Decision:** Alimemazine is used for enteral sedation in NUTH paediatric ITUs and very occasionally for sedation in other paediatric patients. Following discussions within NUTH around its use in non ITU patients it has been suggested that it should be used only in cases where promethazine has failed. Alimemazine will be retained on formulary as a red drug for these indications. Existing patients can continue to be prescribed in primary care until there is an opportunity to review their treatment.
Formulary review		Chapter 2 review undertaken. Formulary to be updated.
Zero range		New cheaper branded generic cream now available as part of range already on the formulary **Decision:** It was agreed to add the new zero cream on to the formulary.
EAMS schemes		Schemes, such as the CDF and EAMS, are not included on formulary due to the temporary nature of the funding. Once drugs are NICE approved they will be added to the formulary. A line will be added to the formulary to say patients may be able to access non-formulary drugs that have been approved in line with these additional funding directions.