North of Tyne and Gateshead Area Prescribing Committee Minutes of a meeting held on Tuesday 11th October 2016 at Northumbria House, Cobalt Business Park, North Tyneside

Present:

Anne-Marie Bailey (AMB)	Senior Medicines Optimisation Pharmacist	NHS Newcastle Gateshead CCG
Pat Bottrill	Lay Representative	
David Campbell (DCa) (Chair)	Chief Pharmacist/Clinical Director for Medicines Management	NHCT
Ian Campbell	Deputy Clinical Director of Pharmacy and Medicines Management	NUTH
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
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
Graham Syers	Prescribing Lead	NHS Northumberland CCG
Simon Thomas (STh)	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

Apologies

Frank McAulay	Associate Medical Director	GHFT
Helena Nettleton	Public Health	Gateshead LA

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

2016/51	**Declarations of interest** No relevant declarations were made. Members were reminded that annual declarations are now due.
2016/52	**Appeals against previous decisions** None.
2016/53	**Minutes and decision summary from previous meetings.** The following documents were accepted as a true record: • Decision summary from 12/7/16. • Minutes from 12/7/16
2016/54	**Matters arising not on the agenda or Action Log.** None
2016/55	**Action Log** The action log was reviewed and will be updated to reflect the following progress: • 2015/73 - Work on Formulary merging is progressing and expected to be completed, with website active, by end Nov. • 2016/25 - Dulaglutide 0.75mg – 1.5mg injection (Trulicity). It had previously been agreed 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. This decision has been revisited and any application should be considered through the FSC, with inclusion of draft guidance outlining the proposed place in therapy within the application. • 2016/25 - Tadalafil 5mg once daily tablets (Cialis). An application for use would need to be submitted through the FSC. • 2016/26 - Shared Care Guidelines for immunosuppressive therapy following liver transplants, paediatric renal transplantation & adult renal transplantation - The repatriation of patients has been taken as far as it can be. There is a very small percentage of patients who continue to receive their medication in Monitored Dosage Systems for whom prescribing and dispensing is still undertaken in the community. A question was raised as to whether this was an appropriate means of addressing trust responsibilities under disability legislation but it was decided that the SCGs currently need to be kept up to date to cover these patients. • 2016/42 - North of Tyne Heart Failure Guideline. AMB to discuss with Gateshead colleagues if these can be endorsed for use in their area and will subsequently contact the Guideline author if there is a desire to rebadge as NoT & Gateshead Guidelines.
2016/56	**Report from the Formulary Sub-committee** Formulary version 6.4 is now available on the APC website. **Minutes and recommendations from the North of Tyne & Gateshead FSC meeting held on 12/9/16:** 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:

	Safinamide 50mg and 100mg tablets (Xadago®) The request for the treatment of adult patients with mid-to late-stage Parkinson's disease, who are experiencing motor fluctuations, as add-on therapy to levodopa, was rejected on the grounds that there is no evidence of benefit over rasagiline and the increase in cost cannot therefore be justified. Mr Lowery informed the committee that an intent to appeal had been flagged. **Glycopyrronium bromide 1mg tablets & 1mg/5ml suspension** Oral glycopyrronium bromide has been requested for use in patients with uncontrolled oral / respiratory secretions / sialorrhoea with conditions such as Motor Neurone Disease (MND). The FSC recognised that drooling is unsightly and distressing for the family but questioned whether other options such as hyoscine patches or inhaled ipratropium could be used in preference and at a lower cost. It was noted that NICE Guidance makes reference to the use of glycopyrronium but not in a technology appraisal and the Guidance was issued before the availability of a licensed product and increased costs. **Decision: Refused** It was felt there was little evidence of efficacy for such a significant cost impact, therefore the subcommittee agreed not to add Glycopyrronium bromide 1mg tablets & 1mg/5ml suspension to the formulary. **Rituximab for Immunobullous Disease** An NHS England policy was issued in the summer and will be followed. A review of previous approvals will be undertaken by the formulary subcommittee to ensure legacy commissioning decisions are in line with national policy statements. **Fosfomycin Sachets** A branded version of fosfomycin sachets is now available which offers significant cost savings over the generic. Fosfomycin sachets will remain on the formulary in their generic form but organisations will highlight to their prescribers when a particular agent should be used over another in order to realise cost savings. A statement will be added to the front of the formulary to support this principle. **Paediatric Macrogol** The formulary entry for macrogols will be generic but organisations will highlight to their prescribers when a particular agent should be used over another in order to realise cost savings.
2016/57	**Nefopam Consultation** Given the lack of evidence to support its use, overall tolerability, toxicity in overdose, and very high cost the North of Tyne and Gateshead Area Prescribing Committee undertook a consultation exercise to help inform a review of the formulary position of nefopam. The majority of respondents favoured keeping nefopam on the formulary, in a restricted capacity, although there was also clear support for complete removal. The committee considered carefully the various views expressed by those who responded to the

	consultation and decided to remove nefopam from the local formulary. This means that moving forwards no new patients will be initiated on nefopam but the committee acknowledged that additional work will need to be undertaken to amend current local pain guidance and give support to clinicians who will need to review existing patients including those with chronic long term pain and reach a shared decision with them about the most appropriate alternative approach to their management. The RDTC agreed to support the guideline review by reviewing the evidence base behind different approaches.
2016/58	**Report from the Medicines Guidelines and Use Group** Minutes from the meeting on 19/09/16 were accepted. **Clinical Guidelines for approval:** • NoT and G Management of common ophthalmological conditions in primary/community care – approved. • Thyroid Regional Assessment and Management Plan - confirmation that the biochemical reference ranges have been agreed across the patch and Gateshead FT clinicians are happy with the content is required but once received this is endorsed for use. • North of Tyne and Gateshead Special Formulae Prescribing Guidance September 2016 – approved subject to minor amendment to the title • Acne Referral Checklist and Guideline • Newcastle Gateshead Chronic Obstructive Pulmonary Disease Guideline – approved. Concern was expressed that one guideline across the whole footprint of the APC had not been agreed. This is the desire for guidance moving forwards. • PCSK9 inhibitor appendix to FATS7 – noted that approval process for this document was through N-TAG. The APC are now just endorsing use in member organisations. It was noted that areas who do not currently commission Betaquant LDL-C testing will need to progress this. • North of Tyne and Gateshead Area Prescribing Committee statement on prescribing intervals -Approved **Shared Care Guideline(s) for approval** • Melatonin for the Management of Sleep – Wake Disorders in Children and Young People. The committee agreed that subject to minor amendments suggested by MGUG being made, this could be approved by chair`s action. It was agreed that MGUG and provider organisations should explore if the role of melatonin in therapy needed reviewed, including treatment duration and cost effectiveness. • Atomoxetine for adults SCG – approved. **Information leaflets for approval** • Antipsychotics information leaflet – approved subject to minor amendments to clarify that the guidance relates to working age adults with psychosis and not behavioural issues in elderly patients with dementia. TB to progress. **Guidance suggested for removal** • Statement re methotrexate on the APC website. The committee wished to retain this guidance subject to updating in relation to duration of prescription. Concern was expressed over the delay in reaching consensus on updated osteoporosis guidelines. It was agreed that the original NoT guidance and

	separate Gateshead guidelines will be reposted on website pending the guideline group agreeing a single document.
2016/59	**Establishing Regional Medicines Optimisation Committees** DC responded to the consultation document on behalf of the committee following feedback. https://www.england.nhs.uk/wp-content/uploads/2016/08/rmoc-proposals-for-establishment.pdf Discussion is needed outside the meeting about how to ensure we have adequate representation at the regional group.
2016/60	**Annual Report** Previously approved by chair's action and circulated to members for onward distribution within their organisations. Election of officers to be reviewed.
2016/61	**NICE Technology Appraisals** The following Technology Appraisals were noted and the recommendations within them will be reflected in the formulary: • HST3 - Ataluren for treating Duchenne muscular dystrophy with a nonsense mutation in the dystrophin gene • TA398 Lumacaftor–ivacaftor for treating cystic fibrosis homozygous for the F508del mutation • TA399 Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts • TA400 Nivolumab in combination with ipilimumab for treating advanced melanoma • TA401 - Bosutinib for previously treated chronic myeloid leukaemia • TA402 - Pemetrexed maintenance treatment for non-squamous non-small-cell lung cancer after pemetrexed and cisplatin • TA403 - Ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer • TA404 - Degarelix for treating advanced hormone-dependent prostate cancer • TA405 - Trifluridine–tipiracil for previously treated metastatic colorectal cancer • TA406 - Crizotinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer • TA407 - Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors • TA408 - Pegaspargase for treating acute lymphoblastic leukaemia • TA409 - Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion • TA410 - Talimogene laherparepvec for treating unresectable metastatic melanoma • TA411 - Necitumumab for untreated advanced or metastatic squamous non-small-cell lung cancer • TA412 - Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases
2016/62	**Northern (NHS) Treatment Advisory Group (N-TAG)** The following recommendations were finalised by N-TAG at their meeting on the 6/9/16 and are now available on the website Latest News | NTAG :

	• Ferric Maltol for IDA in IBD patients • FreeStyle Libre Glucose monitoring system • Eluxadoline for treatment of IBS-D The formulary will be updated to reflect those recommendations
2016/63	**NHS England** The following NHS England communications were noted and will be reflected in the formulary: • SSC1630 Policy Statement letter - Everolimus (Votubia) for treatment of angiomyolipomas • SSC1632 Provider Letter HIV Antiretroviral Commissioning for Value ARV • SSC1636 Clinical Guidance on alternative options for oral prophylaxis in Hereditary Angioedema • SSC1637 NICE Technology Appraisal 387: Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated • SSC1638 Ceritinib for previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer • SSC1639 NICE TA 396 Trametinib in combination with dabrafenib • SSC1640 NICE TA 400: Nivolumab in combination with ipilimumab for treating advanced melanoma • SSC1641 - Cancer Drugs Fund: National CDF Cohort List • SSC1641 – Pemetrexed • SSC1641 - Trifluridine • SSC1642 NICE Technology Final Appraisal Determination: Talimogene laherparepvec for treating unresectable metastatic melanoma • SSC1643 NICE TA 392: Adalimumab for treating moderate to severe hidradenitis suppurativa • SSC1644 NICE Technology FAD: Crizotinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer' • SSC1646 Palivizumab (To reduce the risk of RSV in High Risk Infants) for the 2016 Vaccination Season' • SSC1647 'NICE TA 402: Pemetrexed maintenance treatment for non-squamous non-small-cell lung cancer after pemetrexed and cisplatin' • SSC1648 EAMS Venetoclax for the treatment of adult patients with CLL • SSC1649 NHS England statement on evolocumab for the treatment of homozygous familial hypercholesterolaemia • SSC1650 Update on the Implementation Timescales for Switch Initiatives.Supplementary information to Specialised Services Circular SSC 1632 (National Anti-Retroviral Therapy Commissioning for Value 2016-2018) • SSC1651 Clarification to Support Implementation of Tenofovir Alafenamide Clinical Commissioning Policy (Ref: NHS England: 16043/P) • SSC1652 Outcome of the CMU tenders for haemophilia blood products and requirements for reimbursement
2016/64	**Chair's action** Approval of annual report.

2016/65	**Any other business** None
2016/66	**Date and time of next meeting(s)** Date and time of next meetings: Tuesday 10th January, 12.30pm Tuesday 11th April 12.30pm Tuesday 11th July 12.30pm Tuesday 10th October 12.30pm Room 4, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.
	Signed: **(Chair of the APC)** **Date:** 10/1/17

North of Tyne & Gateshead Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 11th October 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				
Tafluprost 15mcg/ml (Saflutan®) UDVs	Retained on formulary			Given the new type of delivery vehicle in Monopost® the ophthalmologists wished to retain tafluprost on the formulary while the tolerability of the Monopost® is assessed. **Decision:** The committee agreed to retain tafluprost on formulary alongside latanoprost subject to a review of usage data after 1 year, at which time a decision will be made as to which preparation will remain on formulary.
Tafluprost/timolol 15mcg/5mg/ml (Taptiqom®) UDVs	✓			It was previously recommended that the request for preservative free tafluprost/timolol UDVs be rejected on the grounds that it was planned to remove tafluprost UDVs from formulary. **Decision:** It was agreed that tafluprost/timolol 15mcg/5mg/ml (Taptiqom®) should be added to formulary but subject to review after 1 year when the position of tafluprost is reviewed.
Brinzolamide/ brimonidine 10mg/2mg/ml (Simbrinza®) Drops	✓			Simbrinza® drops have been requested as a third line 'add on' for use in a small cohort of patients at the very end of medical management. It was previously recommended that the product was rejected on the grounds it is much more expensive than the individual formulations however patients using this product would see a reduction of 4-6 drops per day and their exposure to preservatives would be halved. Concerns were raised that this would set a precedent for the approval of other, less cost effective, combination products. It was agreed that approval has been given in this case only because the increase cost is relatively small and this is a patient subgroup where some simplification of the medication regime would be beneficial. **Decision:** The committee agreed to add Brinzolamide/brimonidine 10mg/2mg/ml (Simbrinza®) drops to the formulary as a 3rd line agent.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Isotretinoin 0.05% gel (Isotrex®) **Clindamycin/Tretinoin 1%/0.025% gel (Treclin®)** **Isotretinoin / Erythromycin 0.05%/2% gel (Isotrexin®)** **Clindamycin/ benzoyl peroxide (Duac gel®)**	✓ C			An application for Treclin was considered at the last Formulary Subcommittee but did not progress because an acne guideline (based on NICE CKS) was being produced by Newcastle Gateshead CCG in conjunction with the dermatology team at the RVI. It was therefore agreed that the request should be deferred until the guideline was finalised and a new submission could be made with all of the products needed to comply with the new guideline. The guideline has now been finalised. **Decision:** The committee approved the addition of the new products to the formulary to support guideline implementation. Statements will be added to the formulary that advise the first line use of the cheaper alcohol based products and restricting topical antibiotics only for use for a limited period and in combination with a topical retinoid or BZPO
2) New Requests				
Methoxyflurane (Penthrox®) Inhalation vapour			✓ R	Methoxyflurane (Penthrox®) is an inhaled analgesic, licensed for relief of moderate to severe acute pain in adult patients with trauma. The relative efficacy compared to other agents is unclear, although it seems to have an onset of action similar to IV morphine. Methoxyflurane was previously withdrawn due to dose related nephrotoxicity and liver toxicity. Penthrox® is contraindicated in patients who have a history of renal impairment or in those with a history of liver toxicity after halogenated hydrocarbon anaesthesia. There have been no cases of nephrotoxicity reported with Penthrox® and the product has been used extensively in Australia, including use by paramedics. Other adverse events are not serious and resolve following discontinuation. The Gateshead QE A&E team has been evaluating Penthrox® recently. The subcommittee felt there may be a place for this treatment before cannulation and acknowledged that it had advantages compared to Entonox. **Decision:** The committee recognises the potential advantage of Penthrox® but decided to defer this application. The applicants will be asked to clarify how the renal safety issues would be dealt with and provide clearly defined criteria for its use. The regulators will be asked for the safety data and considered in conjunction with any data collected at Gateshead QE A&E.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Safinamide 50mg and 100mg tablets (Xadago®)		✓		Safinamide is a highly selective MAO-B inhibitor with additional mechanisms of action. It is licensed for the treatment of adult patients with mid-to late-stage Parkinson's disease who are experiencing motor fluctuations. It is used as add-on therapy to levodopa. No head to head studies have been undertaken. In two placebo controlled studies patients receiving safinamide had an extra 30-60 minutes of 'on' time per day. In a further study that assessed the impact on dyskinesia there was a trend towards improvement compared to placebo but this was not statistically significant. Safinamide is significantly more expensive than rasagiline which has recently come off patent. **Decision**: The request was rejected on the grounds that there is no evidence of benefit over rasagiline and the increase in cost cannot therefore be justified.
3) New formulations & extensions to use				
Dexmedetomidine (intranasal)	✓ R			Intranasal dexmedetomidine has been requested for pre-operative sedation in anxious children at risk of respiratory depression in whom midazolam is contraindicated, or in those who have failed pre-operative sedation with other agents. This is an unlicensed indication/route of administration. For pre-medication small RCTs suggest that intranasal dexmedetomidine 1-2 mcg/kg appears to be of similar efficacy to midazolam and ketamine. Intranasal dexmedetomidine appears to be well tolerated however its use is associated with modest reductions in heart rate and blood pressure. Two case reports exist for significant events related to bradycardia, although the patients fully recovered. **Decision:** Approved for premedication as per the request. The child's carers must be adequately consented regarding the unlicensed use of this medication.
Phenylephrine hydrochloride 5.4mg and tropicamide 280 micrograms ophthalmic insert (Mydriasert®)	✓ R			Mydriasert® is licensed for pre-operative mydriasis or for diagnostic purposes. Mydriasert® appears to give similar levels of mydriasis at 60 minutes compared to the commonly used drop regimens and be of similar tolerability. The rate of release from the Mydriasert® insert delivers similar quantities to those seen with multiple dosing with the corresponding drops. The Newcastle Eye Centre wishes to carry out a short term evaluation with Mydriasert® to assess the impact on patient flow and nursing time **Decision:** The committee agreed to add Mydriasert® to formulary on a temporary basis. This would be for 6 months after which an evaluation regarding impact on patient flow and nursing time should be received by the subcommittee.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Glycopyrronium bromide 1mg tablets & 1mg/5ml suspension		✓		Oral glycopyrronium bromide has been requested for use in patients with uncontrolled oral / respiratory secretions / sialorrhoea with conditions such as Motor Neurone Disease (MND). Glycopyrronium has been used by this service for several years as an unlicensed medicine. It has recently been licensed for the treatment of peptic ulcer, with the price increasing substantially. The licensed products postdate the NICE clinical guideline that recommends it as treatment option in MND. The evidence shows that patients do experience an improvement in the symptoms of drooling. The subcommittee recognised that drooling is unsightly and distressing for the family and questioned whether other options such as hyoscine patches should be used in preference. After discussion it was felt this treatment was unlikely to be cost effective. **Decision:** Refused. It was felt there was little evidence of efficacy for such a significant cost impact, therefore the subcommittee agreed not to add Glycopyrronium bromide 1mg tablets & 1mg/5ml suspension to the formulary.
Macrogols (paediatric Laxido®)	See notes			A paediatric version of Laxido® is now available, and as with the adult version it offers cost savings compared to Movicol® Paediatric. **Decision**: Paediatric macrogol products will be added generically and organisations will highlight to their prescribers if they wish any one agent to be used over another in order to realise cost savings.
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC1630 Policy Statement letter - Everolimus (Votubia) for treatment of angiomyolipomas	✓ R			The formulary will reflect the policy outlined in this circular
SSC1632 Provider Letter HIV Antiretroviral Commissioning for Value ARV	✓ R			The formulary will reflect the policy outlined in this circular
SSC1636 Clinical Guidance on alternative options for oral prophylaxis in Hereditary Angioedema	✓ R			The formulary will reflect the policy outlined in this circular

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
SSC1637 NICE Technology Appraisal 387: Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated	✓ R			The formulary will reflect the policy outlined in this circular
SSC1638 Ceritinib for previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer	✓ R			The formulary will reflect the policy outlined in this circular
SSC1639 NICE TA396 Trametinib in combination with dabrafenib	✓ R			The formulary will reflect the policy outlined in this circular
SSC1640 NICE TA 400: Nivolumab in combination with ipilimumab for treating advanced melanoma	✓ R			The formulary will reflect the policy outlined in this circular
SSC1641 Cancer Drugs Fund: National CDF Cohort List				The formulary will reflect the policy outlined in this circular
SSC1641 Pemetrexed maintenance treatment for non-squamous non-small-cell lung cancer after pemetrexed and cisplatin	✓ R			The formulary will reflect the policy outlined in this circular
SSC1641 Trifluridine–tipiracil hydrochloride for previously treated metastatic colorectal cancer	✓ R			The formulary will reflect the policy outlined in this circular
SSC1642 NICE Technology Final Appraisal Determination: Talimogene laherparepvec for treating unresectable metastatic melanoma	✓ R			The formulary will reflect the policy outlined in this circular
SSC1643 NICE TA 392: Adalimumab for treating moderate to severe hidradenitis suppurativa	✓ R			The formulary will reflect the policy outlined in this circular

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
SSC1644 NICE Technology FAD: Crizotinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer	✓ R			The formulary will reflect the policy outlined in this circular
SSC1646 Palivizumab (To reduce the risk of RSV in High Risk Infants) for the 2016 Vaccination Season	✓ R			The formulary will reflect the policy outlined in this circular
SSC1647 NICE TA 402: Pemetrexed maintenance treatment for non-squamous non-small-cell lung cancer after pemetrexed and cisplatin	✓ R			The formulary will reflect the policy outlined in this circular
SSC1648 EAMS Venetoclax for the treatment of adult patients with CLL	✓ R			The formulary will reflect the policy outlined in this circular
SSC1649 NHS England statement on evolocumab for the treatment of homozygous familial hypercholesterolaemia	✓ R			The formulary will reflect the policy outlined in this circular
SSC1650 Update on the Implementation Timescales for Switch Initiatives. Supplementary information to Specialised Services Circular SSC 1632 (National Anti-Retroviral Therapy Commissioning for Value 2016-2018)				The formulary will reflect the policy outlined in this circular
SSC1651 Clarification to Support Implementation of Tenofovir Alafenamide Clinical Commissioning Policy (Ref: NHS England: 16043/P)				The formulary will reflect the policy outlined in this circular
SSC1652 Outcome of the CMU tenders for haemophilia blood products and requirements for reimbursement				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Rituximab for Immunobullous Disease	✓ R			NHS England policy will be followed. A review of previous approvals will be undertaken to ensure legacy commissioning decisions are in line with national policy statements.
Isovuconazole				Isovuconazole has been added to the NHS England High Cost drugs list for use as per "agreed Trust guidelines". A formulary application will be required for clinical governance purposes.
5) Products considered by NICE				
HST3 - Ataluren for treating Duchenne muscular dystrophy with a nonsense mutation in the dystrophin gene	✓ R			The formulary will reflect the position outlined in the TAG
TA398 Lumacaftor–ivacaftor for treating cystic fibrosis homozygous for the F508del mutation	✓ R			The formulary will reflect the position outlined in the TAG
TA399 Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts	✓ R			The formulary will reflect the position outlined in the TAG
TA400 Nivolumab in combination with ipilimumab for treating advanced melanoma	✓ R			The formulary will reflect the position outlined in the TAG
TA401 Bosutinib for previously treated chronic myeloid leukaemia	✓ R			The formulary will reflect the position outlined in the TAG
TA402 Pemetrexed maintenance treatment for non-squamous non-small-cell lung cancer after pemetrexed and cisplatin	✓ R			The formulary will reflect the position outlined in the TAG
TA403 Ramucirumab for previously treated locally advanced or metastatic non-small-cell lung cancer	✓ R			The formulary will reflect the position outlined in the TAG
TA404 Degarelix for treating advanced hormone-dependent prostate cancer	✓			The formulary will reflect the position outlined in the TAG

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA405 Trifluridine–tipiracil for previously treated metastatic colorectal cancer	✓ R			The formulary will reflect the position outlined in the TAG
TA406 Crizotinib for untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer	✓ R			The formulary will reflect the position outlined in the TAG
TA407 Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors	✓ R			The formulary will reflect the position outlined in the TAG
TA408 Pegaspargase for treating acute lymphoblastic leukaemia	✓ R			The formulary will reflect the position outlined in the TAG
TA409 Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion	✓ R			The formulary will reflect the position outlined in the TAG
TA410 Talimogene laherparepvec for treating unresectable metastatic melanoma	✓ R			The formulary will reflect the position outlined in the TAG
TA411 Necitumumab for untreated advanced or metastatic squamous non-small-cell lung cancer	✓ R			The formulary will reflect the position outlined in the TAG
TA412 Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases	✓ R			The formulary will reflect the position outlined in the TAG
6) Northern (NHS) Treatment Advisory Group (N-TAG)				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Ferric Maltol for IDA in IBD patients	✓ R			The Northern (NHS) Treatment Advisory Group recommends the use of oral Ferric Maltol as an alternative option in patients with mild to moderate IDA with IBD who have tried at least two oral ferrous salts and have a reported intolerance to oral ferrous salts due to adverse effects after an adequate trial. Initiation and prescribing of Ferric Maltol should be carried out by an IBD specialist.
FreeStyle Libre Glucose monitoring system	✓ R			The Northern (NHS) Treatment Advisory Group recommends the use of FreeStyle Libre Flash Glucose Monitoring System as an option for continuous glucose monitoring (CGM) only and for patients who fulfil the NICE criteria for CGM and as per the North East and Cumbria CGM guidelines.
Eluxadoline for treatment of IBS-D		✓		The Northern (NHS) Treatment Advisory Group does not recommend the use of eluxadoline for the treatment of diarrhoea dominant IBS.
7) Appeals against earlier decisions by the APC				
None				
8) Miscellaneous decisions by the APC				
Nefopam	See notes			Given the lack of evidence to support its use, overall tolerability, toxicity in overdose, and very high cost the North of Tyne and Gateshead Area Prescribing Committee have decided to remove nefopam from the local formulary. No new patients will be initiated on nefopam. Work will be undertaken to amend pain guidance and give support to clinicians who will need to review existing patients to determine the best course of action for them.
Fosfomycin Sachets	See notes			A branded version of fosfomycin sachets is now available which offers significant cost savings over the generic. **Decision**: Fosfomycin sachets will remain on the formulary in their generic form but organisations will highlight to their prescribers when a particular agent should be used over another in order to realise cost savings. A statement will be added to the front of the formulary to support this principle.