North of Tyne and Gateshead Area Prescribing Committee
Minutes of a meeting held on Tuesday 10th April 2018 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
Sue Dickinson (SD)	Director of Pharmacy	RDTC
Neil Gammack	Chief Pharmacist	GHFT
Matt Grove	Consultant Rheumatologist and Head of Service	NHCT
Ann Gunning		North of Tyne and Gateshead LPCs
Matthew Lowery (ML)	Formulary and Audit Pharmacist	NUTH
Neil Morris (NM)	Medical Director	Newcastle Gateshead CCG
Sheetal Sundeep	Consultant Microbiologist	NHCT
Graham Syers	Prescribing Lead	Northumberland CCG
Simon Thomas (STh)	Consultant Clinical Pharmacologist	NUTH
Susan Turner	Medicines Optimisation Pharmacist	NECS

Apologies

Tim Donaldson	Trust Chief Pharmacist/Associate Director of Medicines Management	NTW
Ruth Evans	Medical Director	North Tyneside CCG
Tomal Karim		South Tyneside and Gateshead LPC
Frank McAulay (FM)	Associate Medical Director	GHFT
Helen Seymour (HS)	Senior Medicines Optimisation Pharmacist	NECS
Neil Watson	Clinical Director of Pharmacy and Medicines Optimisation	NUTH

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

2018/21	**Declarations of interest** None.
2018/22	**Appeals against previous decisions** None.
2018/23	**Minutes and decision summary from previous meeting.** The following documents were accepted as a true record: • Decision summary from 09/01/18. • Minutes from 09/01/18.
2018/24	**Matters arising not on the agenda or Action Log.** None.
2018/25	**Action Log** The action log was reviewed and will be updated to reflect the following: • 2017/02 - Audit of oral glycopyrronium bromide in patients with uncontrolled oral / respiratory secretions / sialorrhoea with conditions such as Motor Neurone Disease (MND). Action overdue. ML to progress. • 2017/56 - APC Guideline on Prescribing PPIs. Action overdue. ML to progress. Primary care to be involved. • 2018/07 - Rituximab approvals. Action overdue. SC to progress. • 2018/09 - AHSN, LA s and Strategic Clinical Networks. Action complete. • 2018/10 - Draft NE&C Regional Guidelines for Diagnosing and Managing CMPA and Lactose Intolerance. Action complete. • 2018/12 - Items which should not be routinely prescribed in primary care: Guidance for CCGs – Formulary update. Action overdue. ML to progress. https://www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-guidance-for-ccgs/ • 2018/19 - Regional AF card. Action complete.
2018/26	**Revised membership and Terms of Reference** Item deferred until July meeting.
2018/27	**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 1/3/18:** 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: **Dexmedetomidine (Dexdor®) – paediatric cardiac surgery** Dexmedetomidine has been requested for use in paediatric cardiac surgery for patients where surgery has a high risk of post-op Junctional Ectopic Tachyarrhythmia (JET) or for those suitable for fast-track surgery. Two studies demonstrate it is efficacious in reducing the occurrence of JET and suggest its use might lead to a reduced extubation time/shorter ICU stay. It was noted that fast track post-op management is difficult with currently available agents and dexmedetomidine may offer advantages. Approval was given subject to clarification of the dosing schedule and confirmation around the licensing position of other agents.

Post meeting note:
The proposed plan is to start the dexmedetomidine infusion, at 0.5 micg/kg/hr, before surgical incision for all patients (fast track and risk for arrhythmias group).
A question had been asked at FSC about the licensed status of other agents used but clarity has now been received that, whilst dexmedetomidine isn't licensed for use in children, it is being used in this context as adjunctive therapy and not replacing the other established agents. The evidence reviewed was for adjunctive treatment.

Decision: Approved
Approved for use in paediatric cardiac surgery for patients where surgery has a high risk of post-op Junctional Ectopic Tachyarrhythmia (JET) or for those suitable for fast-track surgery. Use in procedural sedation is not supported.

Corticosteroid Foam enemas
The increased cost of prednisolone foam enemas has prompted a formulary review. The gastroenterology teams support having budesonide and hydrocortisone as first line options.

Decision:
Prednisolone foam enemas should be removed from the formulary with budesonide and hydrocortisone being equal first choice.
Further work with the gastroenterology leads will be undertaken to produce patient information leaflets and advice for GPs on steps to take when reviewing patients currently on prednisolone.

Items which should not be routinely prescribed in primary care: Guidance for CCGs
https://www.engage.england.nhs.uk/consultation/items-routinely-prescribed/

Recommendations will be reflected in the formulary and work progressed to ensure prescribers reflect these in their prescribing practice.
Data demonstrating prescribing rates for the three months Dec 2017-Feb 2018 for member CCGs are included at the end of these minutes.
The top 5 products, in terms of spend, across the CCG areas are lidocaine patches, once daily tadalafil, liothyronine, trimipramine and immediate release fentanyl.
Initial focus was agreed for lidocaine patches, once daily tadalafil and liothyronine. All member organisations undertook to communicate the recommendations included in the publication and to ensure clinicians would treat patients in line with these.

Liothyronine (including Armour Thyroid and liothyronine combination products)
The national guidance states that:

- Prescribers in primary care should not initiate liothyronine for any new patient
- Individuals currently prescribed liothyronine should be reviewed by a consultant NHS endocrinologist with consideration given to switching to levothyroxine where clinically appropriate.
- A local decision, involving the Area Prescribing Committee and informed

by National guidance, should be made regarding arrangements for on-going prescribing of liothyronine. This should be for individuals who, in exceptional circumstances, have an on-going need for liothyronine as confirmed by a consultant NHS endocrinologist.

The British Thyroid Association (BTA) advises that a small proportion of patients treated with levothyroxine continue to suffer with symptoms despite adequate biochemical correction.

In these circumstances, where levothyroxine has failed and in line with BTA guidance, endocrinologists providing NHS services may recommend liothyronine for individual patients after a carefully audited trial of at least 3 months duration of liothyronine.

In terms of existing patients, a process of review will be needed.

Some discussion has already taken place with the endocrinology team at Northumbria. It is recognised that the total number of patients receiving liothyronine on prescription across the area is small in relation to the total number of patients receiving thyroid replacement therapy but that they accounted for a disproportionate amount of spend. The committee agreed that referral criteria and a patient letter for patients currently on liothyronine will be produced to help progress these recommendations. Primary care will identify patients currently in receipt of liothyronine and liaise with secondary care colleagues to agree if referral for additional specialist review is appropriate or can be undertaken by a review of notes where a patient has been recently seen.

Once daily tadalafil

The national guidance advises that prescribers in primary care should not initiate once daily tadalafil for any new patient and that there should be support for prescribers in deprescribing once daily tadalafil in all patients.

This links with meeting note 2018/34.

Whilst the formulary already reflects the national, and N-TAG, guidance primary care colleagues expressed concern that they frequently get requests to prescribe once daily tadalafil and therefore members representing secondary care agreed to take this opportunity to re-emphasise the position to colleagues and to ask clinical leads to ensure that patients would be treated in line with both the N-TAG and national recommendations.

Lidocaine plasters

The national guidance states that:

- Prescribers in primary care should not initiate lidocaine plasters for any new patient (apart from exceptions below)
- Prescribers should be supported in deprescribing lidocaine plasters in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
- If, in exceptional circumstances, there is a clinical need for lidocaine plasters to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.

These recommendations do not apply to patients who have been treated in line with NICE CG173 *Neuropathic pain in adults: pharmacological management in non-specialist settings* but are still experiencing neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia). Members will ensure that all clinicians are aware of the guidance and that patients should be treated in line with this.

2018/28	**Conditions for which over the counter items should not routinely be prescribed in primary care** https://www.england.nhs.uk/medicines/conditions-for-which-over-the-counter-items-should-not-routinely-be-prescribed/ NHS England recently carried out a public consultation on reducing prescribing of over-the-counter medicines for minor, short-term health concerns. In the year prior to June 2017, the NHS spent approximately £569 million on prescriptions for medicines which can be purchased over the counter from a pharmacy and other outlets such as supermarkets. These prescriptions include items for a condition: • That is considered to be **self-limiting** and so does not need treatment as it will heal of its own accord; • Which lends itself to **self-care**, i.e. that the person suffering does not normally need to seek medical care but may decide to seek help with symptom relief from a local pharmacy and use an over the counter medicine. Vitamins/minerals and probiotics were also been included in the consultation proposals as items of limited clinical effectiveness which are of high cost to the NHS.CCGs had asked for a nationally coordinated approach to the development of commissioning guidance in this area to ensure consistency and address unwarranted variation. The formulary will be reviewed to ensure that products included solely for conditions listed are removed. A series of implementation tools to support CCGs in implementing this guidance are under development and will be used as they become available. The guidance applies to everyone who is not covered by the general or condition-specific exceptions listed in the guidance document. In relation to the exceptions, it is important to highlight: • The guidance does not apply to people with long-term or more complex conditions who will continue to get their usual prescriptions. • People who receive free prescriptions will not automatically be exempt from the guidance. • For patients where the clinician considers that their ability to self-manage is compromised as a consequence of medical, mental health or significant social vulnerability; these patients will continue to receive prescriptions for over the counter items subject to the item being clinically effective. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties. The committee noted this guidance, the requirement for formulary update, and the need for a consistent approach across the health economy to ensure that patients are not passed around the system in an attempt to access medicines on prescription for conditions covered by this guidance. Members will ensure that the guidance is communicated to clinicians and teams in their organisation. Minor ailment schemes will need to be reviewed to ensure they are consistent with the advice although AG highlighted that pharmacists have demonstrated

	through NHS111 referrals into CPRS that they have used these schemes appropriately and are well placed to make appropriate decisions around use of NHS resources. In the CPRS pilot 35% of referrals led to advice only, 30% led to OTC sale of medication, and only 6% led to use of an NHS funded minor ailments scheme. The remaining referrals needed onward signposting. It was suggested that the reference to clinical discretion of the prescriber could also apply to pharmacists.
2018/29	**Interface Issues** **Dermatology specials** ML informed the committee that NUTH are seeing an increasing amount of refusals from GP practices to prescribe unlicensed specials despite them being listed on the formulary as green/green plus. He was seeking assurance that this was not CCG policy. CCG members gave assurance that, where there is no alternative licensed product suitable for patient care, unlicensed products listed on the formulary could be considered for use.ML suggested that there may be further opportunity to consider how these types of medications are supplied to patients.
2018/30	**Report from the Medicines Guidelines and Use Group** No meeting had been held. It was agreed to extend the expiry date of the following guidance to end Sept 2018. • Atomoxetine Shared Care Guidance for Attention Deficit Hyperactivity Disorder (ADHD) in adults • Atomoxetine Shared Care Guidance for Attention Deficit Hyperactivity Disorder (ADHD) in children and young people • Dexamfetamine Shared Care Guideline for ADHD (Adults) • Dexamfetamine Shared Care Guideline for ADHD (Children and Young People) • Lisdexamfetamine Shared Care Guideline for ADHD (Adults) • Lisdexamfetamine Shared Care Guideline for ADHD (Children and Young People) • Melatonin Shared Care Guidance for the Management of Sleep – Wake Disorders in Children and Young People • Methylphenidate Shared Care Guidance for Attention Deficit Hyperactivity Disorder (ADHD) in children and young people and Giggle Incontinence in children aged 8 to 16 years • Methylphenidate Shared Care Guidance for Attention Deficit Hyperactivity Disorder (ADHD) in adults There is currently no secretarial support to this committee. NM agreed to convene a small working group to explore what support was needed and if this was an appropriate time to consider a review of the terms of reference and membership.
2018/31	**Regional Antimicrobial Guidance** • The committee endorses use of this guideline once SS`s comments have been taken into account. Concerns in relation to the responsibility for prescribing in the event of influenza prophylaxis following an outbreak in a care home were raised. Work is underway to clarify with PHE where this sits.
2018/32	**Responsibility for prescribing between Primary & Secondary/Tertiary Care – NHS England publication** The committee noted the contents of this document, including the requirement

	for a minimum of 7 days medication to be supplied on discharge unless clinically inappropriate. Member organisations stated they usually supplied up to 28 days as original pack dispensing was in place.
2018/33	**RMOC** Members have been informed of the RMOC function on the SPS website. DC questioned whether the RMOCs had a role to play in ensuring a consistent approach to shared care and agreed to write to the committee asking for consideration to be given to this. It was agreed that there may still be a need for local implementation but there is a potential role in offering guidance as to which products should be considered suitable for the development of shared care guidance. RMOCs are encouraging LDMs to engage with them following publication of the RMOC work plan.
2018/34	**Northern (NHS) Treatment Advisory Group (N-TAG)** The approved minutes from November 2017 were received by the committee. The following recommendation was finalised by NTAG at their meeting on 27/02/18 and are now available on the website http://ntag.nhs.uk/html/latest_news.html : • **Daily vs on-demand PDE-% inhibitors for management of erectile dysfunction following treatment for prostate cancer.** The Northern (NHS) Treatment Advisory Group recommends that, on the basis of evidence available, there was no evidence to recommend the use of daily dosing over on-demand dosing of PDE5 inhibitors, and there was no evidence that tadalafil was superior to sildenafil. On this basis NTAG recommends on-demand dosing using the PDE5 inhibitor with the lowest acquisition cost; currently this is generic sildenafil. This supports the recommendation in the national guidance noted in meeting note 2018/27. The formulary already reflects this recommendation but additional work will be undertaken to ensure clinicians are aware that this is the CCG commissioning policy.
2018/35	**NICE Technology Appraisals** The following Technology Appraisals were noted and the recommendations within them will be reflected in the formulary: • TA160 - Raloxifene for the primary prevention of osteoporotic fragility fractures in postmenopausal women. Published October 2008, updated February 2018. Guidance on strontium ranelate and etidronate have been removed because these drugs are no longer marketed in the UK. • TA161 - Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women Published October 2008, updated February 2018. Guidance on strontium ranelate and etidronate have been removed because these drugs are no longer marketed in the UK. • TA464 - Bisphosphonates for treating osteoporosis. Published August 2017, updated February 2018 • TA495 - Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer • TA496 - Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer

	• TA497 - Golimumab for treating non-radiographic axial spondyloarthritis • TA498 - Lenvatinib with everolimus for previously treated advanced renal cell carcinoma • TA499 - Glecaprevir–pibrentasvir for treating chronic hepatitis C • TA500 - Ceritinib for untreated ALK-positive non-small-cell lung cancer • TA501 - Intrabeam radiotherapy system for adjuvant treatment of early breast cancer • TA502 - Ibrutinib for treating relapsed or refractory mantle cell lymphoma • TA503 - Fulvestrant for untreated locally advanced or metastatic oestrogen-receptor positive breast cancer – negative appraisal. • TA504 - Pirfenidone for treating idiopathic pulmonary fibrosis • TA505 - Ixazomib with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma • TA506 - Lesinurad for treating chronic hyperuricaemia in people with gout - negative appraisal • TA507 - Sofosbuvir–velpatasvir–voxilaprevir for treating chronic hepatitis C • TA508 - Autologous chondrocyte implantation using chondrosphere for treating symptomatic articular cartilage defects of the knee • TA509 - Pertuzumab with trastuzumab and docetaxel for treating HER2-positive breast cancer • TA510 - Daratumumab monotherapy for treating relapsed and refractory multiple myeloma- guidance • TA511 Brodalumab for treating moderate to severe plaque psoriasis • TA512 Tivozanib for treating advanced renal cell carcinoma • TA513 Obinutuzumab for untreated advanced follicular lymphoma • TA514 Regorafenib for previously treated advanced hepatocellular carcinoma • TA515 Eribulin for treating locally advanced or metastatic breast cancer after 1 chemotherapy regimen • TA516 Cabozantinib for treating medullary thyroid cancer
2018/36	**NHS England** The following NHS England communications were noted and will be reflected in the formulary: • SSC1818_rFVIII 2018 - Letter • SSC1819 - NICE Final Appraisal Determination: Ixazomib with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma • SSC1820 - NICE Technology Appraisal Final Appraisal Determination: Ibrutinib for treating relapsed or refractory mantle cell lymphoma • SSC1821 - NICE Technology Appraisal 478: Brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma • SSC1822 - Early Access to Medicines Scheme – Nivolumab for treatment of adult patients with advanced or recurrent gastric or Gastro-oesophageal Junction (GEJ) cancer after two or more prior systemic therapies • SSC1823 Emicizumab for routine prophylaxis of bleeding episodes in patients - Provider Letter

	previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer.
2018/37	**Chair's action** None
2018/38	**Any other business** None
	Date and time of next meeting(s) Tuesday 10th July 12.30pm Room 4, Northumbria House, Unit 7/8 Silver Fox Way, Cobalt Business Park, North Tyneside.
	Signed: **Date:** 10/7/18 (Chair of the APC)

- SSC1824 - Rituximab for chronic inflammatory demyelinating neuropathy, multifocal motor neuropathy, vasculitis of the peripheral nervous system and IgM paraprotein-associated demyelinating neuropathy
- SSC1825 - NHS England Approval Urgent Clinical Commissioning Policy Statement for the use of pembrolizumab for drug-resistant gestational trophoblastic neoplasia
- SSC1826 Primary Care Responsibilities for private Hormone Treatment for transgender patients
- SSC1827 - NICE Technology Appraisal Final Appraisal Determination: Daratumumab monotherapy for treating relapsed and refractory multiple myeloma
- SSC1828 - NICE Technology Appraisal 488: Regorafenib for previously treated unresectable or metastatic gastrointestinal stromal tumours
- SSC1829 Autologous chondrocyte implantation ACI - Provider Letter
- SSC1830 - NICE Technology Appraisal Final Appraisal Determination: Pertuzumab with trastuzumab and docetaxel for treating HER2-positive metastatic or locally recurrent unresectable breast cancer
- SSC1832 - NICE Technology Appraisal Final Appraisal Determination: Tivozanib for treating advanced renal cell carcinoma
- SSC1833 - NICE Technology Appraisal Final Appraisal Determination: Obinutuzumab for untreated advanced follicular lymphoma
- SSC1834 - NICE Technology Appraisal Final Appraisal Determination: cabozantinib for treating medullary thyroid cancer
- SSC1835 - NICE Technology Appraisal Final Appraisal Determination: lenvatinib and sorafenib for treating differentiated thyroid cancer after radioactive iodine
- SSC1836
    - Managed Access Agreement for asfotase alfa for the treatment of hypophosphatasia
    - Asfotase alfa for the treatment of patients with paediatric-onset hypophosphatasia – adult expert centres
    - Asfotase alfa Provider Letter to all Trusts who are NOT expert centres
- SSC1839 - Clinical Commissioning Policy: Levofloxacin nebuliser solution for chronic pseudomonas lung infection in cystic fibrosis (All ages)
- SSC1841 - NICE Technology Appraisal Final Appraisal Determination: Avelumab for treating metastatic Merkel cell carcinoma
- SSC1843 - Deep Brain Stimulation for Refractory Epilepsy
- SSC1844 - Not Routine Clinical Commissioning Policy: Keratoprosthesis for corneal blindness (URN 1618)
- SSC1847 - Biosimilar Trastuzumab
- SSC1849 Pembrolizumab for locally advanced or metastatic urothelial carcinoma - Provider Letter
- SSC1850 - Early Access to Medicines Scheme: Volanesorsen as an adjunct to diet for the treatment of adult patients with familial chylomicronaemia syndrome
- SSC1851 - NICE TA 496: Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer
- SSC1852 - NICE TA 495: Palbociclib with an aromatase inhibitor for

Items which should not be routinely prescribed in primary care

Issued during December 2017 - February 2018 within Newcastle Gateshead CCG, North Tyneside CCG & Northumberland CCG

Medicine Category	NEWCASTLE GATESHEAD CCG				NORTH TYNESIDE CCG				NORTHUMBERLAND CCG				TOTAL			
	Items	NIC	Actual Cost	No. of identifiable patients	Items	NIC	Actual Cost	No. of identifiable patients	Items	NIC	Actual Cost	No. of identifiable patients	Items	NIC	Actual Cost	No. of identifiable patients
Co-Proxamol	93	£23,233	£21,540	34	15	£2,200	£2,040	5	16	£2,345	£2,175	6	**124**	**£27,779**	**£25,754**	**45**
Dosulepin	2,233	£3,975	£3,809	565	850	£1,704	£1,630	238	1,607	£3,875	£3,661	456	**4,690**	**£9,554**	**£9,100**	**1,259**
Glucosamine and Chondroitin	6	£211	£196	2	0	£0	£0	0	0	£0	£0	0	**6**	**£211**	**£196**	**2**
Herbal Medicines	3	£10	£9	1	1	£4	£3	1	11	£34	£33	5	**15**	**£48**	**£45**	**7**
Homeopathy	7	£34	£32	6	2	£33	£31	2	0	£0	£0	0	**9**	**£67**	**£62**	**8**
Immediate Release Fentanyl	40	£12,264	£11,375	11	86	£14,993	£13,909	6	50	£18,326	£16,994	11	**176**	**£45,583**	**£42,278**	**28**
Lidocaine Plasters	674	£51,308	£47,592	309	284	£22,528	£20,895	139	377	£24,930	£23,128	171	**1,335**	**£98,766**	**£91,616**	**619**
Liothyronine	37	£12,209	£11,324	13	38	£24,527	£22,742	14	55	£27,729	£25,709	21	**130**	**£64,465**	**£59,775**	**48**
Lutein and Antioxidants	6	£74	£68	4	2	£21	£19	1	3	£17	£15	1	**11**	**£111**	**£103**	**6**
Non-LVM	0	£0	£0	0	0	£0	£0	0	4	£13	£12	3	**4**	**£13**	**£12**	**3**
Omega-3 Fatty Acid Compounds	228	£5,931	£5,511	62	137	£3,005	£2,795	41	399	£9,390	£8,723	136	**764**	**£18,326**	**£17,029**	**239**
Once Daily Tadalafil	211	£14,042	£13,028	76	59	£4,101	£3,804	28	176	£10,635	£9,864	72	**446**	**£28,778**	**£26,696**	**176**
Oxycodone and Naloxone Combination Product	164	£9,024	£8,375	30	33	£878	£817	3	23	£1,650	£1,531	8	**220**	**£11,553**	**£10,723**	**41**
Paracetamol and Tramadol Combination Product	16	£110	£103	8	23	£171	£160	7	3	£43	£40	2	**42**	**£324**	**£303**	**17**
Perindopril Arginine	52	£628	£583	22	60	£991	£920	34	120	£1,512	£1,403	58	**232**	**£3,131**	**£2,906**	**114**
Prolonged-release Doxazosin	354	£4,289	£3,993	136	412	£4,924	£4,582	157	724	£6,894	£6,418	238	**1,490**	**£16,106**	**£14,993**	**531**
Rubefacients (excluding topical NSAIDs)	1,475	£7,649	£7,110	848	290	£2,067	£1,920	162	214	£1,329	£1,234	123	**1,979**	**£11,045**	**£10,265**	**1,133**
Travel Vaccines	222	£3,275	£3,036	46	84	£1,117	£1,035	15	162	£2,039	£1,891	59	**468**	**£6,430**	**£5,962**	**120**
Trimipramine	49	£25,528	£23,668	14	33	£9,009	£8,356	8	23	£13,289	£12,321	8	**105**	**£47,826**	**£44,345**	**30**
TOTAL	5,870	£173,794	£161,354	2172	2,409	£92,272	£85,658	848	3,967	£124,049	£115,152	1368	12,246	£390,115	£362,164	4,388

NB: Figures for items, quantity and net ingredient cost are based on all prescribing. Patient numbers only include patients who could be identified during processing activities and may only account for a proportion of the items displayed

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 April 2018.**

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				
Insulin Degludec (Tresiba®) – Paediatric use.	✓ G+			Insulin Degludec was requested for use in children who cannot tolerate the sting associated with insulin glargine and in children and teenagers requiring supervised administration/flexibility around administration times. Since the last meeting the applicant has provided precise description of clinical characteristics of paediatric patients who would be offered degludec. It was felt that ensuring increased compliance with an insulin regime, at a small additional cost, was likely to be cost effective. **Decision: Approved** The request for insulin degludec was approved for children who cannot tolerate the glargine sting, patients with poor control on the high HbA1c pathway and patients/parents with unpredictable lifestyles (e.g. shift workers, students). Ongoing approval is subject to audit in April 2019 demonstrating that inclusion criteria have been adhered to and that improved outcomes have been demonstrated.
2) New Requests				
Citric acid 0.6mol/L (Nebulised)			✓	Citric acid 0.6mol/L has been requested for cough-reflex testing (CTR) in stroke patients with dysphagia as part of initial swallowing assessment. Patients who fail CRT are then referred for more invasive swallow assessment with VFSS or FEES. The quality of the evidence is poor. Higher concentrations (0.6 - 0.8 mol/L) are associated with a higher false negative rate, with 0.4mol/L being the optimum concentration for sensitivity and specificity. Additional information has been requested in respect of how citric acid fits into swallowing assessment pathway and clarification of the strength to be used. **Decision:** The request for citric acid for cough reflex testing was deferred.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
3) New formulations & extensions to use				
Dexmedetomidine injection (Dexdor®)	✓ 			Dexmedetomidine has been requested for use in paediatric cardiac surgery for patients where surgery has a high risk of post-op Junctional Ectopic Tachyarrhythmia (JET) or for those suitable for fast-track surgery. Two studies demonstrate it is efficacious in reducing the occurrence of JET and suggest its use might lead to a reduced extubation time/shorter ICU stay. It was noted that fast track post-op management is difficult with currently available agents and dexmedetomidine may offer advantages. Use is unlicensed. **Decision:** The request for dexmedetomidine in paediatric cardiac surgery was approved. Its use in procedural sedation is not supported.
HPV Vaccine (Gardasil®)	✓ 			HPV Vaccine (Gardasil®) has been requested for therapeutic vaccination in the treatment of recurrent respiratory papillomatosis in children and adults. Current treatment is repeated surgical debridement under a general anaesthetic to keep the airway patent and maintain voice quality. Case reports show partial or full remission in some adults and children and a reduction in the number of surgical interventions. This vaccine has a good safety profile. Girls vaccinated for recurrent respiratory papillomatosis should still be vaccinated again as per the national cervical cancer prevention programme. **Decision:** The request for HPV vaccine (Gardasil®) for the treatment of recurrent respiratory papillomatosis in children and adults was approved.
Atomoxetine 100mg capsules and 4mg/ml oral solution	✓ 			Atomoxetine 100mg capsules have been requested for use in patients requiring high doses (e.g. above 80mg daily), whereas the 4mg/ml oral solution has been requested for patients with more complex needs e.g. younger patients and those with swallowing difficulties. The capsules are expected to be cost neutral, and potentially cost saving, but this is dose dependent. The liquid is more expensive and the estimated numbers expected to be treated was questioned. **Decision:** The requests for the atomoxetine 100mg capsules and 4mg/ml oral solution were approved but the applicant will be asked to provide an audit on use of the liquid for 6 months to ensure strict initiation criteria are adhered to.
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC1818_rFVIII 2018				The formulary will reflect the SSC
SSC1819 - NICE Final Appraisal Determination: Ixazomib with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma				The formulary will reflect the SSC
SSC1820 - NICE Technology Appraisal Final Appraisal Determination: Ibrutinib for treating relapsed or refractory mantle cell lymphoma				The formulary will reflect the SSC
SSC1821 - NICE Technology Appraisal 478: Brentuximab vedotin for treating relapsed or refractory systemic anaplastic large cell lymphoma				The formulary will reflect the SSC

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
SSC1822 - Early Access to Medicines Scheme – Nivolumab for treatment of adult patients with advanced or recurrent gastric or Gastro-oesophageal Junction (GEJ) cancer after two or more prior systemic therapies				The formulary will reflect the SSC
SSC1823 Emicizumab for routine prophylaxis of bleeding episodes in patients				The formulary will reflect the SSC
SSC1824 - Rituximab for chronic inflammatory demyelinating neuropathy, multifocal motor neuropathy, vasculitis of the peripheral nervous system and IgM paraprotein-associated demyelinating neuropathy				The formulary will reflect the SSC
SSC1825 - NHS England Approval Urgent Clinical Commissioning Policy Statement for the use of pembrolizumab for drug-resistant gestational trophoblastic neoplasia				The formulary will reflect the SSC
SSC1826 Primary Care Responsibilities for private Hormone Treatment for transgender patients				The formulary will reflect the SSC
SSC1827 - NICE Technology Appraisal Final Appraisal Determination: Daratumumab monotherapy for treating relapsed and refractory multiple myeloma				The formulary will reflect the SSC
SSC1828 - NICE Technology Appraisal 488: Regorafenib for previously treated unresectable or metastatic gastrointestinal stromal tumours				The formulary will reflect the SSC
SSC1829 Autologous chondrocyte implantation ACI				The formulary will reflect the SSC
SSC1830 - NICE Technology Appraisal Final Appraisal Determination: Pertuzumab with trastuzumab and docetaxel for treating HER2-positive metastatic or locally recurrent unresectable breast cancer				The formulary will reflect the SSC
SSC1832 - NICE Technology Appraisal Final Appraisal Determination: Tivozanib for treating advanced renal cell carcinoma				The formulary will reflect the SSC
SSC1833 - NICE Technology Appraisal Final Appraisal Determination: Obinutuzumab for untreated advanced follicular lymphoma				The formulary will reflect the SSC
SSC1834 - NICE Technology Appraisal Final Appraisal Determination: cabozantinib for treating medullary thyroid cancer				The formulary will reflect the SSC
SSC1835 - NICE Technology Appraisal Final Appraisal Determination: lenvatinib and sorafenib for treating differentiated thyroid cancer after radioactive iodine				The formulary will reflect the SSC
SSC1836 - Managed Access Agreement for asfotase alfa for the treatment of hypophosphatasia • Asfotase alfa for the treatment of patients with paediatric-onset hypophosphatasia – letter to adult expert centres • Asfotase alfa Provider Letter to all Trusts who are NOT expert centres				The formulary will reflect the SSC
SSC1839 - Clinical Commissioning Policy: Levofloxacin nebuliser solution for chronic pseudomonas lung infection in cystic fibrosis (All ages)				The formulary will reflect the SSC
SSC1841 - NICE Technology Appraisal Final Appraisal Determination: Avelumab for treating metastatic Merkel cell carcinoma				The formulary will reflect the SSC
SSC1843 - Deep Brain Stimulation for Refractory Epilepsy				The formulary will reflect the SSC
SSC1844 - Not Routine Clinical Commissioning Policy: Keratoprosthesis for corneal blindness (URN 1618)				The formulary will reflect the SSC
SSC1847 - Biosimilar Trastuzumab				The formulary will reflect the SSC
SSC1849 Pembrolizumab for locally advanced or metastatic urothelial carcinoma				The formulary will reflect the SSC

Product	Decision Approved | Refused | Deferred	Comments/notes
SSC1850 - Early Access to Medicines Scheme: Volanesorsen as an adjunct to diet for the treatment of adult patients with familial chylomicronaemia syndrome		The formulary will reflect the SSC
SSC1851 - NICE TA 496: Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer		The formulary will reflect the SSC
SSC1852 - NICE TA 495: Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer		The formulary will reflect the SSC
5) Products considered by NICE		
TA160 - Raloxifene for the primary prevention of osteoporotic fragility fractures in postmenopausal women. Published October 2008, updated February 2018.		Guidance on strontium ranelate and etidronate has been removed because these drugs are no longer marketed in the UK. The formulary will reflect the NICE Guidance
TA161 - Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women. Published October 2008, updated February 2018.		Guidance on strontium ranelate and etidronate have been removed because these drugs are no longer marketed in the UK. The formulary will reflect the NICE Guidance
TA464 - Bisphosphonates for treating osteoporosis. Published August 2017, updated February 2018		The formulary will reflect the NICE Guidance
TA495 - Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer		The formulary will reflect the NICE Guidance
TA496 - Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer		The formulary will reflect the NICE Guidance
TA497 - Golimumab for treating non-radiographic axial spondyloarthritis		The formulary will reflect the NICE Guidance
TA498 - Lenvatinib with everolimus for previously treated advanced renal cell carcinoma		The formulary will reflect the NICE Guidance
TA499 - Glecaprevir–pibrentasvir for treating chronic hepatitis C		The formulary will reflect the NICE Guidance
TA500 - Ceritinib for untreated ALK-positive non-small-cell lung cancer		The formulary will reflect the NICE Guidance
TA501 - Intrabeam radiotherapy system for adjuvant treatment of early breast cancer		The formulary will reflect the NICE Guidance
TA502 - Ibrutinib for treating relapsed or refractory mantle cell lymphoma		The formulary will reflect the NICE Guidance
TA503 - Fulvestrant for untreated locally advanced or metastatic oestrogen-receptor positive breast cancer – negative appraisal.		The formulary will reflect the NICE Guidance
TA504 - Pirfenidone for treating idiopathic pulmonary fibrosis		The formulary will reflect the NICE Guidance
TA505 - Ixazomib with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma		The formulary will reflect the NICE Guidance
TA506 - Lesinurad for treating chronic hyperuricaemia in people with gout - negative appraisal		The formulary will reflect the NICE Guidance
TA507 - Sofosbuvir–velpatasvir–voxilaprevir for treating chronic hepatitis C		The formulary will reflect the NICE Guidance
TA508 - Autologous chondrocyte implantation using chondrosphere for treating symptomatic articular cartilage defects of the knee		The formulary will reflect the NICE Guidance
TA509 - Pertuzumab with trastuzumab and docetaxel for treating HER2-positive breast cancer		The formulary will reflect the NICE Guidance

Product	Decision (Approved / Refused / Deferred)	Comments/notes
TA510 - Daratumumab monotherapy for treating relapsed and refractory multiple myeloma- guidance		The formulary will reflect the NICE Guidance
TA511 Brodalumab for treating moderate to severe plaque psoriasis		The formulary will reflect the NICE Guidance
TA512 Tivozanib for treating advanced renal cell carcinoma		The formulary will reflect the NICE Guidance
TA513 Obinutuzumab for untreated advanced follicular lymphoma		The formulary will reflect the NICE Guidance
TA514 Regorafenib for previously treated advanced hepatocellular carcinoma		The formulary will reflect the NICE Guidance
TA515 Eribulin for treating locally advanced or metastatic breast cancer after 1 chemotherapy regimen		The formulary will reflect the NICE Guidance
TA516 Cabozantinib for treating medullary thyroid cancer		The formulary will reflect the NICE Guidance

6) Northern (NHS) Treatment Advisory Group (N-TAG)

Daily vs on-demand PDE-% inhibitors for management of erectile dysfunction following treatment for prostate cancer.	The Northern (NHS) Treatment Advisory Group recommends that on the basis of evidence available there was no evidence to recommend the use of daily dosing over on-demand dosing of PDE5 inhibitors, and there was no evidence that tadalafil was superior to sildenafil. On this basis NTAG recommends on-demand dosing using the PDE5 inhibitor with the lowest acquisition cost; currently this is generic sildenafil. The formulary will reflect the N-TAG Guidance.

7) Appeals against earlier decisions by the APC

None

8) Miscellaneous decisions by the APC

Inhaler review	The following options and recommendations from the inhaler review group were discussed and approved: • Triple therapy – both Trelegy® Ellipta and Trimbow® will be included on the formulary with Trelegy® Ellipta as first choice. • ICS/LABA – positioning of the budesonide/formoterol and other ICS/LABA inhalers remains unchanged • LAMA – as the price of Respimat® MDI version of tiotropium has reduced significantly, and is now licensed for asthma, it was agreed to include this on the formulary.
Corticosteroid foam enemas	The increased cost of prednisolone foam enemas has prompted a formulary review. **Decision:** It was agreed that prednisolone foam enemas should be removed from the formulary with budesonide and hydrocortisone being equal first choice. Further work with gastroenterology will be undertaken to produce patient information leaflets and advice for GPs on steps to take when reviewing patients currently on prednisolone.

Product	Decision Approved | Refused | Deferred	Comments/notes
Formulary Review		**Chapter 3 – Respiratory** **03.07 Mucolytics** Acetylcysteine – a licensed preparation, which is cheaper than the unlicensed preparation, is now available and should be included on formulary. **03.08 Aromatic Inhalations** Benzoin Tincture Compound –remove from formulary. **Chapter 5 – Antibiotics** **05.01.01.03** Co-fluampicil – very rarely used and not on the primary care guidelines. Remove from formulary.
Items which should not be routinely prescribed in primary care: Guidance for CCGs		Recommendations to be reflected in the formulary and work progressed to ensure prescribers reflect this in their prescribing practice.