NHS

North of Tyne, Gateshead and North Cumbria
Area Prescribing Committee

April 2020 meeting.
Papers shared and considered via email, and chairs action taken to approve, due to COVID-19.

2020/18	**Declarations of interest** None made
2020/19	**Appeals against previous decisions** None
2020/20	**Minutes and decision summary from previous meeting.** The following documents were accepted as a true record: • Decision summary from 14/01/20. • Minutes from 14/01/20.
2020/21	**Matters arising not on the agenda or Action Log.** None.
2020/22	**Action Log** The action log was reviewed and will be updated to reflect the following: • 2019/28 Cinacalcet APC guidance. It was noted in January that the guidance was being reviewed by North Cumbria and chairs action could be taken if they are happy with it. Chairs action has now been taken and the document uploaded to APC website. Action completed. • 2020/06 Dexamfetamine for narcolepsy – Agenda item. Approved, remove from action log.
2020/23	**Report from the Formulary Sub-committee** The formulary website is available at North of Tyne, Gateshead and North Cumbria Area Prescribing Committee Formulary. **Minutes and recommendations from the North of Tyne, Gateshead and North Cumbria FSC meeting held on 13/2/20:** The above minutes and recommendations were approved. The following specific points were highlighted: **Sucralfate suspension** Sucralfate suspension was removed from the formulary in July 2017 following a chapter review on the grounds that it was a low use product and, at the time, no licensed product available. It has subsequently been requested for: • Short term use post Radio Frequency Ablation (RFA) for Barret's Oesophagus & Endoscopic Mucosal Resection (RMR). • Bile Reflux (usually post oesophagectomy) in patients in patients who have failed PPI treatment. Approx. 20 – 60 patients per year. Northumbria confirmed that they also use it for stomal ulceration and biliary gastritis in approx. 10-15 patients per year. A literature search didn't identify any studies that specifically looked at the use of sucralfate in patients with bile reflux following oesophagectomy but it has

been compared it to PPI in other patient groups. A licensed product is now available from Alliance Healthcare.

Decision
The committee approved the addition of sucralfate suspension to the formulary with a 'Red' status for post RFA and EMR patients and a 'Green Plus' status for bile reflux and stomal ulceration patients.

Sativex for MS spasticity – status
Sativex for MS spasticity is recommended by NICE. The guideline states that a shared care agreement should be in place. The MS team will initiate treatment, review response after 4 weeks (using a VAS score) and perform an annual review thereafter. A short shared care guideline should be produced that contains information regarding:

- the clinical criteria for initiation
- the requirement for a review by the MS team prior to transfer to the GP
- the requirement for specialist annual review thereafter.

Decision
The committee agreed that Sativex for MS spasticity should be given an 'Amber' status once the SCG is approved. Until then prescribing will be retained in secondary care.

Ingenol mebutate
Following a series of safety alerts ingenol mebutate has lost its market authorisation and will therefore be removed from formulary.

Silicone scar preparations
The committee clarified that the use of silicone scar gel preparations was previously approved for use by the 'Burns Team and Scar Clinic' and the formulary will be amended to reflect this. Currently the formulary only states "burns team".

GLP-1 agonist RAG status
Clarity has been requested around the RAG status of GLP-1 agonists as some have a 'Green' status while other have a 'Green Plus' status.
The committee agreed that the RAG status of all GLP1 drugs on formulary should be changed to 'Green' subject to local guidelines being followed.

The MHRA drug safety alerts were received for November 2019, December 2019 and January 2020 and the formulary will be amended to reflect:

- Domperidone for nausea and vomiting: lack of efficacy in children; reminder of contraindications in adults and adolescents.

Compassionate use / Early Access / Free of charge schemes.
Following discussion at the North East Pharmacy Procurement Group it had been suggested that the regional procurement pharmacist should have oversight of these agreements and could sign these on behalf of Trusts. Concerns were raised about where the liability would lie with this approach and, following further discussion and national advice, the consensus now is that the procurement group should have sight of such schemes, for transparency and awareness of industry practices, but any signing should continue to be taken at Trust level.

	The former will allow feedback to NHSE/NICE etc. on pricing policies and practices of industry whilst the latter will ensure that current governance processes via APCs/DTCs are maintained. ML indicated that NUTH are happy with this process for CCG commissioned drugs but that the vast majority of such schemes fall under NHSE Spec Comm and, as they encourage participation in these schemes, such a process would not be used by them for these.
2020/24	**Low Carbon inhalers** The NHS long-term plan for England has set out plans to increase the use of lower carbon footprint inhalers. The plan says this could help reduce carbon emissions in the NHS in England by 4%. The NHS Sustainable Development Unit has estimated that 3.5% of the NHS's total carbon footprint comes from pMDIs which have a carbon footprint approximately 18 times that of DPIs. Data from Open Prescribing demonstrates that the CCGs in our APC area all have a significantly lower rate of MDI prescribing as a % of all inhaler prescribing than the national average. In fact at the end of Qtr. 2 19/20 North Tyneside, Northumberland and Newcastle Gateshead CCGs are the 3 lowest prescribing CCGs of MDIs (excluding salbutamol) nationally with North Cumbria also demonstrating relatively low use. The committee has been asked to endorse a formulary statement that encourages the use of low carbon inhalers wherever this is clinically appropriate. The committee was happy to do so and a statement to this effect will be added to the formulary.
2020/24	**Report from the Medicines Guidelines and Use Group** Draft minutes from meeting held on 24/2/20 were received and noted. • Guidance agreed to retire: o North of Tyne/Gateshead guidelines for detection, management and referral of adults with kidney disease o Memantine shared care guidance – now incorporated in Cognitive enhancing medications. • Guidance/documents to be approved: o Dexamfetamine shared care guideline o North of Tyne recommendations for symptom management in renal patients (including symptom management at the end of life) o Cinacalcet shared care guideline o Catheter formulary o Vitamin D quick reference guide – update o Brand name prescribing – update
2020/25	**Opiate/pain management sub-group** Minutes from the meeting held on 4/3/20 were received by the committee. This included data up to the end Qtr.3. 19/20. The data demonstrates that more progress seems to have been made on influencing gabapentinoid prescribing than opioid prescribing. An action from the group was to present a position statement to APC members around opiate prescribing. This was developed and shared with members via email in March. Chairs action was subsequently taken to approve it. Organisations were asked to give proper consideration to the statement as the expectation is that all would be signed up to it and be taking actions to demonstrate that commitment. It will be published on the APC website.

2020/26	**RMOC** The following RMOC recommendations were received : • Advisory Statement: Standard Principles for Medicines Prior Approval Forms (January 2020) • Advisory Statement Sequential Use of Biologic Medicines (January 2020) • Free of Charge (FOC) Medicines Schemes: Updated RMOC Advice for adoption as local policy (January 2020) The APC received and noted these recommendations. The third of these documents cross references to item 2020/23.
2020/27	**ICS update** The ICS OHS Board has been stood down until further notice. The board is due to discuss the ongoing support for the Pharmacy and Medicines Strategy Group and a decision on this will now be delayed. In the meantime scheduled meetings of the ICS Pharmacy and Medicines Strategy Group and the Joint Pharmacy Workforce and Talent Work stream will not proceed.
2020/28	**Northern (NHS) Treatment Advisory Group (N-TAG)** http://ntag.nhs.uk/ The following recommendation was finalised by NTAG at their meeting on the 25th February 2020: • Voke® Inhaler Nicotine Replacement Therapy for Smoking Cessation The following recommendations were updated by NTAG at their meeting on the 25th February 2020 and are now available on the website: • Sativex® for the treatment of non-MS pain • Transcutaneous vagus nerve stimulation for treatment of cluster headache and migraine • Lycra Garments for the management of cerebral palsy and other neurological or musculoskeletal conditions The following recommendations were archived by NTAG at their meeting on the 25th February 2020 as they are now superseded by NICE TAs: • Patiromer cation exchange resin for hyperkalaemia • Ozurdex® dexamethasone ocular implant for posterior segment uveitis (NETAG) • Biologic drugs for treatment-refractory moderate to severely active ulcerative colitis in younger patients (to avoid colectomy) The formulary will reflect these recommendations.
2020/29	**NICE Technology Appraisals** The formulary will be amended to reflect the following: • TA617 Lusutrombopag for treating thrombocytopenia in people with chronic liver disease needing a planned invasive procedure • TA618 Atezolizumab with carboplatin and nab-paclitaxel for untreated advanced non-squamous non-small-cell lung cancer (terminated appraisal) • TA619 Palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer • TA620 Olaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer • TA621 Osimertinib for untreated EGFR mutation-positive non-small-cell lung cancer • TA622 Sotagliflozin with insulin for treating type 1 diabetes

	• TA623 Patiromer for treating hyperkalaemia: • TA624 Peginterferon beta-1a for treating relapsing–remitting multiple sclerosis • TA625 Recombinant human parathyroid hormone for treating hypoparathyroidism (terminated appraisal)
2020/30	**NHS England** The following NHS England communications were noted and will be reflected in the formulary: • Specialised Services circulars : o SSC2117 - Specialised Commissioning Update February to April o SSC2119 - Not for Routine Commissioning Policy for Telotristat for treating carcinoid syndrome diarrhoea in adults o SSC2122 - Human plasma derived C1 esterase inhibitors for Hereditary Angioedema o SSC2125 - NICE Technology Appraisal Final Appraisal Determination - Lenalidomide with rituximab for previously treated follicular lymphoma o SSC2126 - Specialised Commissioning Update March 2020 o SSC2128 - Two drug regimen policies for the treatment of HIV-1 Dolutegravir rilpivirine and dolutegravir lamivudine o SSC2129 - NICE Technology Appraisal Final Appraisal Determination - Pembrolizumab for previously treated advanced or metastatic urothelial cancer (CDF review TA519) o SSC2130 - Mercaptamine hydrochloride viscous eye drops for corneal cystine deposits in people aged older than 2 years
2020/31	**Chair's action** **Completion of AMR survey sent on behalf of Richard Seal, Regional Chief Pharmacist (NHS England and NHS Improvement) on behalf of the APC** The NHS Commissioning Support Units (CSUs) have been commissioned by NHSE/I to support a number of key Regional Medicines Optimisation Committee (RMOC) work streams. Arden & GEM CSU are leading on Antimicrobial Resistance (AMR) for the collaborative, with one element being the intelligence gathering of views around the challenges facing clinicians and organisations around AMR and the practical help and resources needed to implement the medicines optimisation elements of the AMR strategy (primary care/out of hospital care), and NICE antimicrobial guidelines in particular. The aim is to inform future work streams and outputs that will practically support everyone working to promote antimicrobial stewardship. **Position statement on the use of opioid medicines – approved.** At the March pain management subgroup it was agreed that it may be helpful to have an APC position statement that could support clinicians when they are having difficult conversations with patients. A draft was circulated to members asking them to consider it and indicate any changes they required. The expectation of members is to ensure that organisations are ultimately all signed up to it and to be taking actions to demonstrate that commitment. .

	Date and time of next meeting(s) Cobalt conference centre, Level 2 Northumbria Healthcare NHS Foundation Trust Northumbria House 7-8 Silver Fox Way Cobalt Business Park North Shields NE27 0QJ Tuesday, 7th July 2020 12:30 pm room 4 (tbc) Tuesday, 13th October 2020 12:30 pm Tea/coffee will be available from 12:15 pm

North of Tyne, Gateshead and North Cumbria Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Tuesday 14th January 2020.**

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				
None				
2) New Requests				
Semaglutide (Ozempic®)	✓ G			Semaglutide is a long acting glucagon-like peptide-1 receptor (GLP1) agonist for the treatment of type 2 diabetes. It has been requested for formulary inclusion on the grounds that the pre-filled pen lasts 1 month compared to the dulaglutide pen which is discarded after the weekly injection. It has been directly compared with dulagutide and exenatide extended release and was associated with statistically significantly greater reductions in HbA1c and weight loss. An indirect comparison with daily liraglutide, exenatide twice-daily or daily dulaglutide showed similar results. It is the same price as the other long acting GLP1 agonists. **Decision:** The committee agreed to add semaglutide (Ozempic®) to the formulary on the condition that extended release exenatide be removed. Existing patients will be able to continue on treatment.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Ostenil Plus®		✓ R		Ostenil Plus® is a combination of sodium hyaluronate with mannitol for intra-articular injection into the knee. It has been requested by North Cumbria Integrated Care Foundation Trust on the grounds that it may reduce the use of rescue medication and delay the need for surgical intervention. Hyaluronic acid intra-articular injections were removed from formulary in 2015 following a "do not use recommendation" by NICE in 2014. The applicant provided two specific references for Ostenil Plus® one of which was published after the NICE review however the evidence from this was study was weak. European guidelines published in 2016 do recommend the use of intra-articular sodium hyaluronate in patients with knee osteoarthritis however this was based on evidence published prior to the NICE review and NICE did still not recommend use. There was no consensus for use across the APC footprint. **Decision:** Application refused.
3) New formulations & extensions to use				
IV Zanamivir (Dectova®)	✓ R			IV zanamivir has been requested by the virologists at Newcastle Hospitals for the treatment of severe influenza in line with its licensed indication e.g. patients who are unable take oral oseltamivir or inhaled zanamivir or in those with resistance to oseltamivir. IV zanamivir has been compared with oral oseltamivir in a phase III superiority study in patients with influenza severe enough to justify hospitalisation. There was no difference in the primary outcome of time to clinical response between IV zanamivir and oral oseltamivir. Therefore the study failed to meet its primary outcome and it was granted a restricted indication by the EMA. **Decision:** i/v zanamivir will be added to the formulary for the treatment of severe influenza on the advice of virology/microbiology/ID only.
LIFT Juice Shot	✓ G			LIFT Juice Shot is a carbohydrate drink for the treatment of hypoglycaemia in children under 10 years. It has been requested by the North Cumbria paediatric diabetes specialists for the treatment of nocturnal hypoglycaemia. This on the grounds that giving a solid glucose source at night can be difficult and that Glucogel® is not always well tolerated by younger children. LIFT Juice Shot has been used in North Cumbria in these circumstances with some success. **Decision**: LIFT Juice Shot will be added to the formulary for the treatment of nocturnal hypoglycaemia in children only.

4) NHS England Specialised Services communications noted and endorsed by APC	
SSC2083 - Specialised Commissioning Update	The formulary will reflect the SSC position
SSC2084 - NICE TA 591: Letermovir for preventing cytomegalovirus disease after a stem cell transplant	The formulary will reflect the SSC position
SSC2085 - NHS England Treatment Criteria for NICE TA 587 guidance: Lenalidomide plus dexamethasone for previously untreated multiple myeloma	The formulary will reflect the SSC position

Product	Decision Approved | Refused | Deferred	Comments/notes
SSC2086 - NICE TA 586 guidance: Lenalidomide plus dexamethasone for multiple myeloma after 1 treatment with bortezomib		The formulary will reflect the SSC position
SSC2087 - Clinical Commissioning Urgent Policy Statement: Antivirals for adults with recent onset (acute) hepatitis. Ref: 170135P		The formulary will reflect the SSC position
SSC2089 - NICE TA FAD: Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer		The formulary will reflect the SSC position
SSC2090 - NICE TA guidance [TA343] Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia		The formulary will reflect the SSC position
SSC2091 - Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) for breast cancer patients		The formulary will reflect the SSC position
SSC2092 - Specialised Commissioning Update		The formulary will reflect the SSC position
SSC2096 - Change in atezolizumab dosing schedule: implications for currently funded indications for adults with non-small cell lung cancer and urothelial cancers		The formulary will reflect the SSC position
SSC2099 - Specialised Commissioning Update - December		The formulary will reflect the SSC position
SSC2100 - Changes to Blueteq registration requirements for patients receiving neo-adjuvant and adjuvant pertuzumab for HER2-positive early-stage breast cancer		The formulary will reflect the SSC position
SSC2101 - NICE Technology Appraisal Final Appraisal Determination: Olaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer (including a review of technology appraisal no. 381)		The formulary will reflect the SSC position
SSC2104 - NICE Technology Appraisal Final Appraisal Determination - palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer		The formulary will reflect the SSC position
SSC2105 - Isatuximab in combination with pomalidomide and dexamethasone for the 4th line treatment of adult patients with relapsed and or refractory multiple myeloma		The formulary will reflect the SSC position
SSC2107 - Maternal intravenous immunoglobulin administration for prevention of alloimmune fetal and neonatal haemochromatosis disease NHS England Reference -1864		The formulary will reflect the SSC position
SSC2111 - Technology Appraisal 614 and 615 - Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome and Dravet syndrome		The formulary will reflect the SSC position
SSC2113 - NHS England update on selected providers for the new Multiple Sclerosis Management Service for Children		The formulary will reflect the SSC position
SSC2114 - NICE Highly Specialised Technology HST11 - Voretigene neparvovec for treating inherited retinal dystrophies caused by RPE65 gene mutations		The formulary will reflect the SSC position
5) Products considered by NICE		
TA604 Idelalisib for treating refractory follicular lymphoma		The formulary will reflect the NICE position
TA605 Xeomin (botulinum neurotoxin type A) for treating chronic sialorrhoea		The formulary will reflect the NICE position

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA606 Lanadelumab for preventing recurrent attacks of hereditary angioedema				The formulary will reflect the NICE position
TA607 Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease				The formulary will reflect the NICE position
TA608 Ibrutinib with rituximab for treating Waldenstrom's macroglobulinaemia (terminated appraisal)				The formulary will reflect the NICE position
TA609 Ramucirumab for treating unresectable hepatocellular carcinoma after sorafenib (terminated appraisal)				The formulary will reflect the NICE position
TA610 Pentosan polysulfate sodium for treating bladder pain syndrome				The formulary will reflect the NICE position
TA611 Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer				The formulary will reflect the NICE position
TA612 Neratinib for extended adjuvant treatment of hormone receptor-positive, HER2-positive early stage breast cancer after adjuvant trastuzumab				The formulary will reflect the NICE position
TA613 Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema in phakic eyes after an inadequate response to previous therapy				The formulary will reflect the NICE position
TA614 Cannabidiol with clobazam for treating seizures associated with Dravet syndrome				The formulary will reflect the NICE position
TA615 Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome				The formulary will reflect the NICE position
TA616 Cladribine for treating relapsing–remitting multiple sclerosis- technology appraisal guidance				The formulary will reflect the NICE position
HST12 Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2				The formulary will reflect the NICE position
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
No meeting to report				
7) Regional Medicines Optimisation Committee (RMOC)				
Prescribing and commissioning of sodium oxybate in adult patients (≥19 years) with narcolepsy with cataplexy.				The committee noted the RMOC position but will continue to reflect the NTAG recommendation in the formulary
Regional Medicines Optimisation Committee (RMOC) Position Statement : Oral vitamin B supplementation in alcoholism November 2019				The formulary is in line with the RMOC recommendations.
8) Appeals against earlier decisions by the APC				
None				

9) Guidelines approved/removed. http://www.northoftyneapc.nhs.uk/guidance/	
Management of heart failure	Guidance retired
Catheter formulary and information sheet	Approved
Blood glucose test strips v2.0	Updated guidance approved
Vitamin B12	Approved
Swallowing difficulties v2.0.	Updated guidance approved
Acne guideline v2.1.	Updated guidance approved
Vitamin D Quick Reference Guide v2.0	Updated guidance approved
10) Miscellaneous decisions by the APC	
Dexamfetamine for narcolepsy	Dexamfetamine was approved for narcolepsy in 2011 with doses less than 30mg given a Green Plus status and doses greater than 30mg given a Red status. However dexamfetamine for ADHD is an Amber drug for all doses. A literature search has been undertaken and no evidence was identified that specifically looked at the differences in safety profile between dexamfetamine doses less than 30mg or greater than 30mg daily for the treatment of ADHD or Narcolepsy. To avoid confusion it is proposed to have dexamfetamine for narcolepsy changed to an Amber status for all doses up to 60mg. **Decision:** The committee agreed that the status of dexamfetamine for narcolepsy will be changed to Amber for all doses up to 60mg daily.
Tadalafil	Tadalafil is currently on the formulary for erectile dysfunction (ED) as a third choice agent after sildenafil and avanafil. Tadalafil is off patent and considerably cheaper therefore it is will now become the second choice agent. **Decision:** Tadalafil is the second choice agent for ED and avanafil will be removed from the formulary.
Melatonin review	Following the availability of new licensed melatonin preparations the subcommittee had been asked to review the melatonin formulations on formulary. In addition to formulation review consideration was given to a recent review referring to long term safety concerns with exogenous melatonin in relation to delayed puberty, and an equivalent fall's risk with exogenous melatonin in elderly patients compared to other hypnotics. The formulary subcommittee, in consultation with appropriate specialist clinicians, concluded that the safety concerns with exogenous melatonin had been overstated. However it was recognised that there was some overprescribing of melatonin and a potential gap in appropriate ongoing review of use. A flow chart to support the prescribing and review of melatonin will be shared across different specialisms and taken through the MGUG before wider distribution to primary care. It was agreed that the drug tariff (DT) **alcohol free** 5mg/5ml unlicensed oral solution should be used as the preferred liquid formulation. **Decision:** The formulary approved preparations will be as follows: • First line: Melatonin 1mg and 5mg modified-release tablets in line with licensed indications only. • Second line: melatonin 2mg modified release tablets • Third line: melatonin 2mg modified release tablets (crushed). • Fourth line : Melatonin 5mg/5ml oral solution (alcohol free) - for patients unable to use crushed tablets

Efudix cream ©	Status change to green agreed following the MHRA safety update relating to ingenol. It was agreed that a standard reference guide to show patients what to expect following application would be helpful. Ingenol status will be changed to RED
Sativex® for MS related spasticity R	Nice have recommended that use in MS related spasticity will be initiated by specialists but may be transferred to primary care for prescribing under a shared care agreement. The APC will retain this as a hospital only drug until the shared care agreement is developed and approved.
Nabilone for chronic pain	Nabilone is currently on formulary for chronic pain but following publication of NICE guidance this will be removed. Existing patients should continue to have access, as per NICE guidance, until they and their clinician feel it is appropriate to stop.