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

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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

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	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 G	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.
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.