North of Tyne, Gateshead and North Cumbria
Area Prescribing Committee

Minutes of the meeting held on Tuesday 14th January 2020

Present:

Pat Bottrill	Lay Representative	
David Campbell (Chair)	Chief Pharmacist/Clinical Director for Medicines Optimisation	NHCT
Ian Campbell	Assistant Director, Pharmacy and Medicines Optimisation	NUTH
Paul Conroy		NoT LPC
Sue Dickinson	Director of Pharmacy	RDTC
Tim Donaldson	Chief Pharmacist/Controlled Drugs Accountable Officer	CNTW
Paul Fieldhouse	Clinical Director of Pharmacy	NCICFT
Neil Gammack	Chief Pharmacist	GHFT
Matt Grove	Consultant Rheumatologist	NHCT
Naeem Iqbal	Prescribing Lead	NTCCG
Steve Llewellyn	Medicines Optimisation Pharmacist	NGCCG
Matthew Lowery	Formulary and Audit Pharmacist	NUTH
Neil Morris	Medical Director	NG CCG
Helen Ridley	Formulary Pharmacist	NHCT
Helen Seymour	Senior Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Graham Syers	Clinical Director of Primary Care	N CCG
Susan Turner	Pharmacist	NECS

Apologies

Sarah Chandler	Lead Clinical Pharmacist – Clinical Informatics, Procurement and Business Information	NHCT
Frank McAuley	Associate Medical Director	GHFT
Simon Thomas	Consultant Clinical Pharmacologist	NUTH
Neil Watson	Clinical Director of Pharmacy and Medicines Optimisation	NUTH

GHFT	Gateshead Health NHS Foundation Trust
NG CCG	Newcastle Gateshead CCG
NT CCG	North Tyneside CCG
NC CCG	North Cumbria CCG
NCICFT	North Cumbria Integrated Care Foundation Trust
NCCG	Northumberland CCG
NoT LPC	North of Tyne Local Pharmaceutical Committee
NHSE	NHS England
NHCT	Northumbria Healthcare NHS Foundation Trust
NECS	North of England Commissioning Support Organisation
CNTWT	Cumbria, Northumberland Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre
ST&G LPC	South Tyneside and Gateshead LPC

2020/01	**Declarations of interest** None declared
2020/02	**Resignation from committee** Frank McAuley has informed the committee that he is moving to NHS Western Isles and therefore will no longer continue to be a member of the APC. The committee acknowledged his significant contribution, particularly his helpful and pragmatic approach during the bringing together of decision making groups 3 or so years ago. DCa has passed on our thanks and best wishes for the future.
2020/03	**Appeals against previous decisions** None to hear but PF informed the committee that Mr Cristian Nita (consultant knee surgeon at North Cumbria Integrated Care FT) intends to submit an appeal regarding the recommendation by the FSC to refuse the application for Ostenil Plus®
2020/04	**Minutes and decision summary from previous meeting.** The following documents were accepted as a true record: • Decision summary from 8/10/19. • Minutes from 8/10/19.
2020/05	**Matters arising not on the agenda or Action Log.** None.
2020/06	**Action Log** The action log was reviewed and will be updated to reflect the following: • 2018/61 Catheter formulary task and finish group – Agenda item: Action complete • 2019/23 Citric acid – cough reflex testing. Evaluation is delayed as a more formal evaluation is being planned. Results are not likely to be available until September 2020. • 2019/24 Items which should not routinely be prescribed in primary care – requires amiodarone and dronedarone shared care guidance. The amiodarone guidance is drafted and should be presented to APC in April. The dronedarone guidance is already in place. • 2019/25 Items which should not routinely be prescribed in primary care - Formulary has been updated to reflect guidance. Action complete. • 2019/28 Cinacalcet – guidance being reviewed by North Cumbria. Chair's action can be taken if they are happy with it. • 2019/53 Melatonin – formulary review complete. • 2019/53 Nursing lead – DC to write to Nicola Allen formally inviting her to join the committee.

2020/07	**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 21/11/19:** The above minutes and recommendations were received by the committee. The summary of decisions made in relation to new product requests is listed in the decision summary. The following specific points were highlighted for further consideration: A catheter formulary has been produced by a task and finish group chaired by Jackie Rees (Nurse Consultant for Continence, NuTH). This was approved and DC will write to Jackie, formally thanking her for her contribution and recognising the challenges that this presented. DC will invite Nicola Allen, Gateshead Health Foundation Trust, to join the committee to represent nursing colleagues. Nursing representation has been missing from the committee in recent months and the committee felt this would add an additional dimension to discussions/decisions. Nicola has initially agreed to lead on the ongoing review of the dressings formulary with organisational support from Neil Frankland. **Semaglutide (Ozempic®)** 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 dulaglutide and exenatide extended release and was associated with statistically significant 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. The FSC agreed to recommend inclusion on the proviso that the diabetologists agreed which of the existing GLP1 agents could be removed from the formulary. ML informed the committee that concensus had subsequently been reached to remove extended release exenatide. **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. **LIFT Juice Shot** 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, with a Green status, for the treatment of nocturnal hypoglycaemia in children only.

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. 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 or greater than 30mg daily for the treatment of ADHD or Narcolepsy. The FSC has proposed that the traffic light status for dexamfetamine for narcolepsy should be changed to amber for all doses up to 60mg. A shared care guideline will be developed.

Decision: The committee agreed that the status of dexamfetamine for narcolepsy will be changed to Amber for all doses up to 60mg daily.

Melatonin

Following the availability of new licensed melatonin preparations the formulary subcommittee had been asked to review the current formulary approved products. In addition to this 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 falls 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. It was recognised, however, 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. The shared care guidance will be updated and expanded to reflect this. 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

NICE guidance NG144 Cannabis-based medicinal products

Nabilone for chronic pain will be removed from the formulary in line with the recommendations of NICE. No new patients will be started on this and there will be a review of effectiveness in existing patients.

Sativex: NICE state that a 4-week trial of THC:CBD (Sativex) spray should be offered to patients to treat moderate to severe spasticity in adults with multiple sclerosis, if:

	• other pharmacological treatments for spasticity are not effective (see the recommendations on spasticity in NICE's guideline on multiple sclerosis in adults) • the company provides THC:CBD spray according to its pay-for-responders scheme After the 4-week trial, THC:CBD spray can be continued if the person has had at least a 20% reduction in spasticity-related symptoms on a 0 to 10 patient-reported numeric rating scale. Treatment with THC: CBD spray should be initiated and supervised by a physician with specialist expertise in treating spasticity due to multiple sclerosis, in line with its marketing authorisation. Sativex will therefore be added to the formulary, in line with these criteria only, as a RED drug until shared care guidance, in line with NICE recommendations, has been developed. The formulary will specifically state that approval is not for chronic pain.
2020/08	**Report from the Medicines Guidelines and Use Group** Draft minutes from meeting held on 2/12/20 were received and noted. Updated terms of reference were accepted. The main change was to remove the requirement for MGUG to maintain a RAG list. Guidelines will have a 3 year review period unless significant new information becomes available that prompts an earlier review. • Guidance to retire: o Management of heart failure • Guidance/documents approved: o Catheter formulary o Catheter info sheet v1.0 It was agreed that the information leaflet will be added to the formulary. Whilst there is lay representation on the APC there had not been specific patient involvement in development of the catheter guidance and formulary. It was felt this may be beneficial when a review is due. It was also noted that two new devices, for which the consumables will be available in tariff in the new year, have been marketed recently. The first is Diveen, an intravaginal tampon designed to reduce urinary stress incontinence. The second is Purewick, an external female catheter. HS has asked NTAG to consider reviewing these products but, in the absence of that, the FSC may need to consider the formulary position before use is accepted. o Blood glucose test strips v2.0 o Vitamin B12. It was acknowledged that there is a significant amount of work to be undertaken if full implementation is to be achieved. This will be a gradual process of review but it was acknowledged that the guidance is helpful and will help inform decisions about new patients. o Swallowing difficulties v2.0. A five year expiry date has been approved for this guidance. o Acne guideline v2.1. o Vitamin D QRG v2.0. This has been updated to exclude patients on cinacalcet.

2020/09	**CNTW – letter from Sunderland/South Tyneside APC** DC informed the committee that he had received a letter from Andrew Berrington, in his role as vice-chair of the Sunderland & South Tyneside ('South of Tyne') APC, about formulary decisions pertaining to Cumbria, Northumberland Tyne & Wear NHSFT. From time to time the South of Tyne APC is faced with scenarios in which decisions are proposed or made at the NoT APC about drugs that will be prescribed in the community on recommendation from CNTW. As CNTW covers a wide area, and several APCs, its prescribing recommendations might be made to General Practitioners in other parts of the region. This creates a problem if their advice refers to drugs that are not on the relevant local formulary. He acknowledged that the converse might arise – the SoT APC might make decisions about CNTW matters that have implications for patients in another area. The CNTW representative to the SoT APC is having discussions within the mental health trust to try to ensure that documents and formulary requests are harmonised internally before forwarding (preferably simultaneously) to relevant APCs. As an extension to that, AB was formally requesting that any formulary-related decisions, or recommendations made about medicines that will be initiated by CNTW, are discussed jointly between the two APCs before a decision is made that might affect both patches. DC had responded to acknowledge that the success of our local arrangements are, in large part, down to the amount of business that gets done outside the formality of meetings and to say he would facilitate, as far as possible, such an approach. The committee discussed the importance of co-operative working whilst not adding unnecessary delay to decision making in either area. Members of the APC sub-committees will liaise with appropriate members of the SoT APC when they think this would be beneficial. As a first step it was suggested that work was undertaken to harmonise the CNS section of the relevant formularies, led by CNTW. TD recognised the potential benefits for his organisation in doing this work but also highlighted that there were similar challenges between North Cumbria and Morecombe Bay. It was noted that NHS England has expressed a desire to move towards a single formulary across the whole ICS. Members of the ICS pharmacy strategy group have discussed the challenges of achieving this, whilst retaining local engagement, with NHS England representatives.
2020/10	**Standardising pathways and Guidelines – AHSN project** The committee received a Final Stakeholder Report from the GP leads in NGCCG who had been working with the AHSN to try and standardise processes across the ICP, and potentially ICS, relating to pathways and guidelines. The complexity of the task was recognised by the committee who await with interest any further update on this work.
2020/11	**Opiate/pain management sub-group** GS updated the committee on progress of this group and actions from the meeting held on 20/11/19. Qtr2. data was received. It was noted that some progress had been made on narrowing the gap between prescribing rates in our area and the rest of England but that there was still work to be done. There is work underway with the AHSN to focus on delivering information to practices that has an emphasis on change management. During the financial year 2020/21 CROP (Campaign to Reduce Opioid Prescribing) reports will be sent to all practices across the AHSN on a bi-monthly basis. These may help facilitate further local discussion on prescribing patterns and how to influence

	change. It is recognised that this is a cross-organisational issue and engagement at all levels of all organisations is necessary to effect change. There may be some learning points from work on anxiolytic prescribing that can be translated across to pain management.
2020/12	**RMOC** The following RMOC recommendations were received : • 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. • RMOC Shared Care Guidance consultation (which includes the following): o a definition of shared care o letter templates to support shared care communications o a shared care monograph o a list of medicines deemed suitable for shared care. This resource has been developed following advice from a shared care working group which comprised primary and secondary care clinicians from across all of the four RMOCs. The RMOC North is seeking comments from APC/formulary committees specifically on the content of these documents. The aim of the resource is to provide a framework to support the seamless sharing of patient care between specialist and primary care prescribers. Comments are required by 30th January from individuals or as a joint APC response. The APC encouraged members to respond individually, or on behalf of their organisations, but will not collate a formal APC response. The committee was disappointed that there hadn't been a move towards a standard national traffic light list or any recommendations about commissioning arrangements.
2020/13	**Northern (NHS) Treatment Advisory Group (N-TAG)** Next meeting February 2020
2020/14	**NICE Technology Appraisals** The formulary will be amended to reflect the following: • TA604 Idelalisib for treating refractory follicular lymphoma • TA605 Xeomin (botulinum neurotoxin type A) for treating chronic sialorrhoea • TA606 Lanadelumab for preventing recurrent attacks of hereditary angioedema • TA607 Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease • TA608 Ibrutinib with rituximab for treating Waldenstrom's macroglobulinaemia (terminated appraisal) • TA609 Ramucirumab for treating unresectable hepatocellular carcinoma after sorafenib (terminated appraisal) • TA610 Pentosan polysulfate sodium for treating bladder pain syndrome • TA611 Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer • TA612 Neratinib for extended adjuvant treatment of hormone receptor-

	positive, HER2-positive early stage breast cancer after adjuvant trastuzumab • TA613 Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema in phakic eyes after an inadequate response to previous therapy • TA614 Cannabidiol with clobazam for treating seizures associated with Dravet syndrome • TA615 Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome • TA616 Cladribine for treating relapsing–remitting multiple sclerosis-technology appraisal guidance • HST12 Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2
2020/15	**NHS England** The following NHS England communications were noted and will be reflected in the formulary: • SSC2083 - Specialised Commissioning Update • SSC2084 - NICE TA 591: Letermovir for preventing cytomegalovirus disease after a stem cell transplant • SSC2085 - NHS England Treatment Criteria for NICE TA 587 guidance: Lenalidomide plus dexamethasone for previously untreated multiple myeloma • SSC2086 - NICE TA 586 guidance: Lenalidomide plus dexamethasone for multiple myeloma after 1 treatment with bortezomib • SSC2087 - Clinical Commissioning Urgent Policy Statement: Antivirals for adults with recent onset (acute) hepatitis. Ref: 170135P • SSC2089 - NICE TA FAD: Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer • SSC2090 - NICE TA guidance [TA343] Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia • SSC2091 - Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) for breast cancer patients • SSC2092 - Specialised Commissioning Update • SSC2096 - Change in atezolizumab dosing schedule: implications for currently funded indications for adults with non-small cell lung cancer and urothelial cancers • SSC2099 - Specialised Commissioning Update - December • SSC2100 - Changes to Blueteq registration requirements for patients receiving neo-adjuvant and adjuvant pertuzumab for HER2-positive early-stage breast cancer • 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) • SSC2104 - NICE Technology Appraisal Final Appraisal Determination - palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer • SSC2105 - Isatuximab in combination with pomalidomide and dexamethasone for the 4th line treatment of adult patients with relapsed and or refractory multiple myeloma

	• SSC2107 - Maternal intravenous immunoglobulin administration for prevention of alloimmune fetal and neonatal haemochromatosis disease NHS England Reference -1864 • SSC2111 - Technology Appraisal 614 and 615 - Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome and Dravet syndrome • SSC2113 - NHS England update on selected providers for the new Multiple Sclerosis Management Service for Children • SSC2114 - NICE Highly Specialised Technology HST11 - Voretigene neparvovec for treating inherited retinal dystrophies caused by RPE65 gene mutations
2020/16	**Chair's action** None
2020/17	**Any other business** 1. MG highlighted an incident relating to methotrexate 10mg tablets. Members agreed that it would be helpful to remind all prescribers about the local and national advice relating to use of 10mg methotrexate tablets. 2. The committee noted that there is NICE guidance in development in relation to Upadacitinib. NICE are expected to publish the FAD in spring 2020. Upadacitinib is a Janus-kinase (JAK) 1 inhibitor that blocks the JAK-signal transducer and activator of transcription (STAT) pathway and inflammatory responses. It is administered orally. Depending on the NICE recommendations there may be implications for clinic capacity.
	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, 21st April 2020 12:30 pm room 4 Tuesday, 7th July 2020 12:30 pm room 4 Tuesday, 13th October 2020 12:30 pm room to confirm Tea/coffee will be available from 12:15 pm
	Signed: **Date:** (Chair of the APC)