North of Tyne, Gateshead and North Cumbria
Area Prescribing Committee

Minutes of the meeting held on Tuesday 12th January 2021
Meeting held via Microsoft Teams

Present:

Nicola Allen	Clinical Lead for Community Services	GHFT
Pat Bottrill	Lay Representative	
Steven Brice	Deputising for Neil Watson	NUTH
David Campbell (Chair)	Chief Pharmacist/Clinical Director for Medicines Optimisation	NHCT
Ian Campbell	Assistant Director, Pharmacy and Medicines Optimisation	NUTH
Sarah Chandler	Formulary Pharmacist	NHCT
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	GP prescribing lead	NTCCG
Steve Llewellyn	Medicines Optimisation Pharmacist	NGCCG
Matthew Lowery	Formulary and Audit Pharmacist	NUTH
Geraint Morris		NoT LPC
Helen Seymour	Senior Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Susan Turner	Pharmacist	NECS

Apologies

Sue Dickinson	Director of Pharmacy	RDTC
Alistair Green	Formulary pharmacist	NHCT
Graham Syers	Clinical Director of Primary Care	N CCG
Simon Thomas	Consultant Clinical Pharmacologist	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

2021/1	**Declarations of interest** None declared. The chairman confirmed that an annual APC declaration would not be required as members completed these within their own organisations. Members will however continue to be asked for any current conflicts at the start of each meeting.
2021/2	**Appeals against previous decisions** Mr Cristian Nita from NCIC trust had been due to attend to present an appeal relating to an earlier application to have Ostenil Plus included in the formulary but was unable to be present. As this appeal hearing had already been re-scheduled more than once the committee agreed that they would be unable to extend the date to hear this appeal further and that a new formulary submission would need to be made before further consideration was given to approval. Application was therefore formally rejected.
2021/3	**Minutes and decision summary from previous meeting.** The following documents were accepted as a true record: • Decision summary from 13/10/20. • Minutes from 13/10/20.
2021/4	**Matters arising not on the agenda or Action Log.** None
2021/5	**Action Log** The action log was reviewed and will be updated to reflect the following: • 2019/23. Citric acid – cough reflex testing. The planned evaluation is developing into a more robust piece of research. If that results in a need for formulary amendment a new application will be presented, including that evidence. Action closed. • 2019/ 23. Testogel Pump Dispensers. The agreed audit has not been completed but it was agreed that the current formulary range offers clinician and patient flexibility and can be maintained. Action closed. • 2019/53. Follitropin delta (Rekovelle®) injection. The addition of Rekovelle® to the formulary was approved in October 2019 for the purposes of a 100 patient evaluation only. The fertility service had paused seeing patients during the early stages of COVID – 19 and therefore the required patient numbers have not been met. Deadline extended to July 2021 • 2019/53. Progesterone 25mg SC/IM Injection (Lubion®). The APC agreed that Lubion® would be added to the formulary for luteal support in patients who have had a previous failed biochemical pregnancy in a FET cycle. This approval is subject to a report of outcomes, back to the formulary subcommittee after 40 patients. The fertility service had paused seeing patients during the early stages of COVID – 19 and therefore the required patient numbers have not been met. Deadline extended to July 2021 • 2020/06. Melatonin guidance. TD confirmed that there was ongoing work in CNTW to update internal trust prescribing guidance. He has also been in touch with NTAG who are to undertake a review of the evidence base for each indication and provide guidance on the need for review when transitioning from adolescence to adulthood. Julie Owens (Northumbria CAMHS team) has agreed to chair a local group that will consider both prescribing and de-prescribing guidance. CNTW will identify a representative to join that group. HS agreed to act as a link between the local and the NTAG work.

2021/6	**Report from the Formulary Sub-committee** MG informed the committee that Dr P McEvedy has resigned from the formulary subcommittee due to working reduced hours. Dr McEvedy was thanked for his contribution and commitment to both the formulary subcommittee, and the APC, over a number of years. 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 3/12/20:** 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: **Methylphenidate for long-term use in post-cancer treatment** Methylphenidate immediate release tablets have been requested for survivors of childhood acute lymphoblastic leukaemia and brain tumours to improve cognitive function. Shared care would be required with secondary care initiating the treatment and carrying out annual reviews and primary care taking over the prescribing responsibility after three months. The formulary subcommittee felt the application had reasonable governance although primary care was concerned about picking up the responsibility of prescribing off label for what is effectively a trial situation and how the transition from paediatric into adult care would be handled. Prior to approval it was agreed that a specific shared care agreement would be required to clarify this is a niche indication and the responsibilities of all involved. **Rosuvastatin – formulary status** The Northern England Evaluation and Lipid Intensification steering group (NEELI) are updating guidance for the use of cholesterol lowering drugs in Northern England. As well as including rosuvastatin as an option in its statin intensity table, the NEELI guidance advises that it may be used as an alternative to atorvastatin for primary or secondary prevention if compatible with another drug therapy. A request to change the status of rosuvastatin from GREEN+ to GREEN was therefore approved. **Oral Vitamin B Supplementation** Recent RMOC guidance around oral vitamin B supplementation, North Cumbria Medicines Optimisation Team have requested a status change, which will enable Vitamin B Compound Strong to be prescribed across both primary and secondary care for the niche situations described in the RMOC guidance https://www.sps.nhs.uk/wp-content/uploads/2019/12/RMOC-position-statement-oral-vitamin-B-supplementation-in-alcoholism-v1.0-1.pdf . The committee approved the status change of oral vitamin B supplementation from RED to GREEN+ only for the situations described in the RMOC guidance.

	Atorvastatin 30mg and 60mg strengths are being introduced to the market at a much higher cost than the original strengths. The formulary will have approved strengths added so that these higher cost variations are not included.
2021/7	**Report from the Medicines Guidelines and Use Group** Draft minutes from meeting held on 7/12/20 were received and noted. Reviewed terms of reference were noted. • Guidance/documents approved: o Cow`s Milk and Protein allergy guidance o Oral nutritional supplements guidance Amiodarone shared care guidance was approved in October. Clarification was sought on action required for existing patients who had been lost to specialist follow up. The committee recognised that there may be some capacity constraints within the specialist services but agreed that the need for a specialist to assess and monitor patients' response to treatment, and the need to continue therapy on at least a 6-monthly basis, stood for all patients. A shared care arrangement should be put in place for all patients.
2021/8	**North ICP Clinical Guidelines Project** Building on the engagement work and outline vision established over the last year, the aim of the North ICP Clinical Guidelines Project is to standardise clinical guidelines across the North ICP area and share these out to primary care via a portal on an established online platform – Clarity TeamNet. Initial work will concentrate on collating and hosting existing guidance. The draft Qtr. 1 update on work to date was received and noted. The APC is happy to be part of the wider stakeholder group and work with the overarching governance group as required.
2021/9	**Opiate/pain management sub-group** Quarter 2 data was received. The group intends to present a "case for change" paper to the ICS management board to try and raise awareness of the wider issues affecting pain and pain management in the ICS population and seek commitment for a unified focus on addressing issues that impact on this. Claire Jones, a Public Health Pharmacy Adviser, from Durham County Council is helping with that work.
2021/10	**RMOC** The following RMOC (South) draft documents had previously been shared with members for comment: • "Buprenorphine long-acting injection: considerations for opioid substitution treatment use in community settings and secure environments in England" available at: https://www.sps.nhs.uk/articles/rmoc-buprenorphine-long-acting-injection-guidance-consultation-running-until-13-11-2020/ "Hydroxychloroquine retinopathy monitoring" available at: https://www.sps.nhs.uk/articles/rmoc-hydroxychloroquine-retinopathy-monitoring-consultation-running-until-13-11-2020/ • "Best value biologic - insulin glargine toolkit" available at: https://www.sps.nhs.uk/articles/rmoc-best-value-biologic-insulin-glargine-toolkit-consultation-running-until-24-12-2020/ MG commented that the Royal College of ophthalmologists have published updated guidance in December 2020 https://www.rcophth.ac.uk/wp-content/uploads/2020/12/Hydroxychloroquine-and-Chloroquine-Retinopathy-

	Monitoring-Guideline.pdf which advise that baseline monitoring is not needed for the majority of patients until 5 years after therapy commences. There is a caveat that monitoring may be started one year after therapy is initiated if additional risk factors exist. This has some resource benefits as it moves the resource implications further down the line and makes the monitoring slightly less intensive than the 2018 guidance. There are ongoing discussions about structure and membership of RMOCs. HS and MG currently represent our area on the RMOC North.
2021/11	**System working** The committee noted the NHS publication titled "Integrating care - Next steps to building strong and effective integrated care systems across England" https://www.england.nhs.uk/wp-content/uploads/2021/01/integrating-care-next-steps-to-building-strong-and-effective-integrated-care-systems.pdf This document outlines potential legislative changes required to build on the route map set out in the *NHS Long Term Plan*, for health and care joined up locally around people's needs. It signals a renewed ambition for greater collaboration between partners in health and care systems to help accelerate progress in meeting our most critical health and care challenges. The committee is both supportive and mindful of these changes. Following on from the above item the committee discussed a Shared care proposition letter received from Dr. Ian Davidson, Chair, County Durham & Tees Valley APC, asking for support in developing a single ICS wide shared care guideline for immune modifying drugs. The committee was supportive in principle but expressed concerns that the driver behind the request was in part due to a desire to address differing commissioning arrangements that exist in different parts of the ICS area. Differing models of service delivery have been built up over several years and the infrastructure supporting such models of care is influenced by many factors including workforce and geography. Challenges faced in some areas, where the commissioning model is different to that in the area where the referral is initiated, will not be able to be fixed by the production of a regional clinical guideline; implementation is key. Despite these reservations the committee is supportive of regional working where possible and MG agreed to link in with the guideline development group as the clinical lead for our area. DC agreed to write to Dr. Davidson outlining both our support, but also our concerns.
2021/12	**Northern (NHS) Treatment Advisory Group (N-TAG)** • Infliximab Subcutaneous (Remsima®) –the previous recommendation has been updated to include reference to license extension for Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and psoriasis plus making reference to recently published NICE evidence summary on infliximab SC in rheumatoid arthritis. http://ntag.nhs.uk/docs/rec/NTAG-Decision-Summary-Infliximab-subcutaneous-Remsima-updated-Aug-2020.pdf The following recommendations were finalised by NTAG at their meeting on the 8th December 2020. The formulary will reflect these recommendations. • Solriamfetol for obstructive sleep apnoea in adults • Solriamfetol for narcolepsy in adults • Teriparatide Biosimilar • Dupilumab and Omalizumab for chronic rhinosinusitis with nasal polyps The following recommendations were updated:

	• Flash Glucose Monitoring – updated to include Learning Disability on insulin as an additional criterion as per latest NHSE criteria for reimbursement • Daily vs on-demand PDE-5 inhibitors for management of erectile dysfunction following treatment for prostate cancer – reviewed and no changes made. The following recommendation has been archived as it is now superseded by NICE: • Liraglutide (Saxenda®) for Obesity in adults
2021/13	**NICE Technology Appraisals** The committee noted NG187 COVID-19 rapid guideline: vitamin D. This guideline covers vitamin D use in the context of COVID-19. The guideline encourages people to follow UK government advice on taking a vitamin D supplement to maintain bone and muscle health. It goes on to state that clinicians should not offer a vitamin D supplement to people solely to prevent COVID-19, except as part of a clinical trial. The APC is supportive of that position. The formulary will be amended to reflect the following: • Early access to medicines scheme (EAMS) scientific opinion: Berotralstat in the treatment of hereditary angioedema • HST13 Volanesorsen for treating familial chylomicronaemia syndrome • TA652 – appraisal terminated • TA653 Osimertinib for treating EGFR T790M mutation-positive advanced non-small-cell lung cancer • TA654 Osimertinib for untreated EGFR mutation-positive non-small-cell lung cancer • TA655 Nivolumab for advanced squamous non-small-cell lung cancer after chemotherapy • TA656 Siponimod for treating secondary progressive multiple sclerosis • TA657 Carfilzomib for previously treated multiple myeloma • TA658 Isatuximab with pomalidomide and dexamethasone for treating relapsed and refractory multiple myeloma • TA659 Galcanezumab for preventing migraine • TA660 Darolutamide with androgen deprivation therapy for treating hormone-relapsed non-metastatic prostate cancer • TA661 Pembrolizumab for untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma • TA663 Venetoclax with obinutuzumab for untreated chronic lymphocytic leukaemia • TA664 Liraglutide for managing overweight and obesity • TA665 Upadacitinib for treating severe rheumatoid arthritis • TA666 Atezolizumab with bevacizumab for treating advanced or unresectable hepatocellular carcinoma • TA667 Caplacizumab with plasma exchange and immunosuppression for treating acute acquired thrombotic thrombocytopenic purpura • TA668 Encorafenib plus cetuximab for previously treated BRAF V600E mutation-positive metastatic colorectal cancer The potential cost implications for CCGs of TA659 Galcanezumab for preventing migraine were noted. Discussions between providers and commissioners are already underway.

2021/14	**NHS England** The following NHS England communications will be reflected in the formulary: • SSC2184 - NICE Technology Appraisal Final Appraisal Determination: darolutamide with androgen deprivation therapy for treating hormone-relapsed non-metastatic prostate cancer • SSC2190 - Early Access to Medicines Scheme – Berotralstat for routine prevention of recurrent attacks of hereditary angioedema (HAE) in adult and adolescent patients aged 12 years and older • SSC2191 - Entrectinib, larotrectinib and genomic testing for neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumours. • SSC2192 - Pharmacogenomic testing for DPYD polymorphisms with fluoropyrimidine therapies. • SSC2192 - policy statement • SSC2195 - NICE Technology Appraisal Final Appraisal Determination - Atezolizumab with bevacizumab for treating advanced or unresectable hepatocellular carcinoma. • SSC2198 Policy revision: plerixafor for stem cell mobilisation in adults and children • SSC2199 Encorafenib plus cetuximab for previously treated BRAF V600E mutation-positive metastatic colorectal cancer • SSC2200 Clinical Commissioning Policy (Revised): Use of defibrotide in severe veno-occlusive disease following stem cell transplant. • SSC2202 Clinical Commissioning Policy: Mercaptamine hydrochloride viscous eyedrops for corneal cystine deposits in people aged older than 2 years – not for routine commissioning. • SSC2203 is regarding NHS England Clinical Commissioning Policy: Sapropterin for Phenylketonuria (all ages). • SSC2205 - Specialised Commissioning Update December 2020 to February 2021 • SSC2206 - acalabrutinib for treating chronic lymphocytic leukaemia • SSC2207 - brigatinib for ALK-positive advanced non-small-cell lung cancer • SSC2208 - NHS England Funding Position for NICE TA439 - Cetuximab and panitumumab for previously untreated metastatic colorectal cancer • SSC2209 - Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis
2021/15	**Chair's action** None taken
2021/16	**Any other business** None raised
	Date and time of next meeting(s) Microsoft Teams • Tuesday 13th April 12.30 – 2.30pm • Tuesday 13th July 12.30 – 2.30pm • Tuesday 12th October 12.30 – 2.30pm