

**North of Tyne, Gateshead and North Cumbria  
Area Prescribing Committee**

**Minutes of the meeting held on Tuesday 2<sup>nd</sup> April 2019 Cobalt Business Park**

**Present:**

Pat Bottrill	Lay Representative	
Ian Campbell	Assistant Director, Pharmacy and Medicines Optimisation	NUTH
Sarah Chandler	Formulary Pharmacist	NHCT
Sue Dickinson	Director of Pharmacy	RDTC
Tim Donaldson	Chief Pharmacist/Controlled Drugs Accountable Officer	NTW
Neil Gammack	Chief Pharmacist	GHFT
Naeem Iqbal	Prescribing Lead	NTCCG
Steve LLewellyn	Senior Medicines Optimisation Pharmacist	NGCCG
Matthew Lowery	Formulary and Audit Pharmacist	NUTH
Frank McAuley	Associate Medical Director	GHFT
Helen Seymour	Senior Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Graham Syers(chair)	Prescribing Lead	NCCG
Simon Thomas	Consultant Clinical Pharmacologist	NUTH
Susan Turner	Pharmacist	NECS
Neil Watson	Clinical Director of Pharmacy and Medicines Optimisation	NUTH

**Apologies**

David Campbell	Chief Pharmacist/Clinical Director for Medicines Optimisation	NHCT
Ruth Evans		NTCCG
Paul Fieldhouse	Clinical Director of Pharmacy Services	NCUHT
Matt Grove	Consultant Rheumatologist and Head of Service	NHCT
Hannah Willoughby	Pharmacist	NGCCG

GHFT	Gateshead Health NHS Foundation Trust
NG CCG	Newcastle Gateshead CCG
NT CCG	North Tyneside CCG
NC CCG	North Cumbria CCG
NCUHT	North Cumbria University Hospitals 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
NTWT	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

2019/18	<p><b>Declarations of interest</b> No declarations were made.</p>
2019/19	<p><b>Appeals against previous decisions</b> None</p>
2019/20	<p><b>Minutes and decision summary from previous meeting.</b> The following documents were accepted as a true record:</p> <ul style="list-style-type: none"> <li>• Decision summary from 9/10/18.</li> <li>• Minutes from 9/10/18.</li> </ul>
2019/21	<p><b>Matters arising not on the agenda or Action Log.</b></p> <p><b>2019/09 Guidelines standardisation</b> HS updated the committee on the outcomes of the meeting convened to improve the creation, distribution, use of and review of clinical guidelines in the out of hospital setting. The meeting notes will be shared with members. Next steps include working with the AHSN to support a project manager and some clinician resource to pull this together for the North ICP. The APC noted the ongoing discussions and will interface our guidance with any new process as required.</p>
2019/22	<p><b>Action Log</b> The action log was reviewed and will be updated to reflect the following:</p> <ul style="list-style-type: none"> <li>• 2017/41 The previous request for povidone-iodine sterile aqueous solution was approved subject to an evaluation, with defined end points guided by WHO guidance, being returned to FSC. Data received by the FSC shows the orthopaedic infection rate has reduced over the years. Over the last 6 months this trend continued following the introduction of wound lavage with sterile aqueous povidone-iodine. The Subcommittee noted it is difficult to detect a significant reduction within 6 months given the low rate of infection, and are happy to approve the continued use of povidone-iodine sterile aqueous solution for wound lavage. Action complete. Remove from action log.</li> <li>• 2017/55 IV lidocaine – pain management. The request for IV lidocaine was approved for post-operative pain management subject to local protocols for use being in place and a review of adverse events being submitted to the FSC after 1 year. Extension to June 2019 FSC.</li> <li>• 2018/27 Insulin Degludec (Tresiba®) – paediatrics. The audit for Insulin Degludec (Tresiba®) has been received by the FSC and demonstrates that the inclusion criteria has been adhered to and improved outcomes have been demonstrated in some patients. Remove from action log.</li> <li>• 2018/60 MHRA Ulipristal advice impacts on the formulary position. The formulary position will be updated for hospital use only in line with the MHRA position. Action closed.</li> <li>• 2018/61 Catheter formulary task and finish group. This is currently being progressed at individual trusts. There is a desire to have one rationalised formulary developed that covers the APC area and recognises the challenges with the handover of care from different trusts to the community when different products are used. ML agreed to approach Jackie Rees, a nurse consultant at NUTH, on behalf of the APC to lead on this work. Work ongoing.</li> <li>• 2017/51 Sufentanil - After a re-examination of the evidence-base, review of some of the practical considerations around the product and the outcome from the pilot the clinical team at Gateshead have come to the</li> </ul>

	<p>position where they are happy to withdraw support for Sufentanil being on the North of Tyne, Gateshead and North Cumbria formulary. A brief statement/ update will be provided to the next formulary sub-committee meeting in May, outlining that intention. Action closed.</p>
<p>2019/23</p>	<p><b>Report from the Formulary Sub-committee</b>  The formulary website is available at <a href="#">North of Tyne, Gateshead and North Cumbria Area Prescribing Committee Formulary</a>.</p> <p><b>Minutes and recommendations from the North of Tyne, Gateshead and North Cumbria FSC meeting held on 14/02/19:</b>  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.</p> <p>The following specific points were highlighted:</p> <p><b>Citric acid – cough reflex testing</b></p> <p>Citric acid 0.6 mol/L, for cough reflex testing (CRT) to identify silent aspiration in stroke patients, was first discussed in March 2018. The request was rejected until more specific information was provided on where it would fit into the dysphagia assessment pathway. The application is supported by the NuTH stroke physicians and further clarity has been provided. Concerns were raised about the poor quality of evidence and that the strength requested differs from that used in some of the studies. It was noted, however, that some other UK units use CRT with 0.6 mol/L citric acid. After discussion it was agreed that there is some potential to using citric acid in this situation but that some more data would be required in 6 months' time.</p> <div style="border: 1px solid black; background-color: #e6f2ff; padding: 5px;"> <p><b>Decision: Approved</b>  <b>Citric acid 0.6mol/L will be added to the formulary on a temporary basis subject to an evaluation being carried out after 6 months showing the outcomes.</b></p> </div> <p><b>Testogel Pump Dispensers</b>  Testogel® pump dispensers have been requested as an addition to the formulary following a recent stock issue with Testogel® sachets. Tostran® gel pumps require double the actuations to achieve the same dose as the Testogel® Pump. The inclusion of this product will aid compliance and will replace the sachets in time.</p> <div style="border: 1px solid black; background-color: #e6f2ff; padding: 5px;"> <p><b>Decision: Approved</b>  The request for Testogel® pump dispensers was approved as a Green Plus drug. This is subject to a 12 month review, at which time, if appropriate, the sachets will be removed from formulary.</p> </div>
<p>2019/24</p>	<p><b>Report from the Medicines Guidelines and Use Group</b>  Draft minutes from the meeting held on 4/ 3/19 were received and noted.</p> <p>The following specific points were noted:</p>

**APC and shared care guidelines**

DC had been approached by the Secretary of County Durham and Darlington LMC outlining a desire to see increased standardisation of the format and clinical advice within shared care documents used across the region. This was discussed at MGUG. It was acknowledged that there are difficulties standardising local guidance across a wider footprint but that this would be beneficial. The difficulties presented by differing care pathways and commissioning arrangements currently make this challenging. It was noted that the RMOCs recognise these challenges and are currently undertaking a piece of work nationally to try and standardise the processes around shared care, at least for an initial number of conditions.

The MGUG Guideline Tracker v0.3 was presented and agreed:

**Guidelines for removal:**

- Agomelatine and high dose venlafaxine leaflets - Information is available in the SPCs and therefore separate guidance is unnecessary.
- Regional antimicrobial guidance - The regional antimicrobial group have advised that the new NICE guidance negates the need for a regional guideline. The APC agreed but will include a link on the APC guidelines section to the NICE guidance as clinicians are in the habit of accessing antimicrobial guidance through the APC website.
- Lidocaine plasters information leaflet
- Gabapentin fast load PIL
- Gabapentin slow load PIL
- Pregabalin fast load PIL
- Pregabalin slow load PIL
- C.Diff assessment tool
- Guanfacine SCG

**Guidelines/Information sheets approved:**

- ADHD guidance - children – defer to July
- ADHD guidance - adults – defer to July
- Menopause guidance - minor updates. Full review pending.
- Urology Guideline – update.

**2019/25****RMOC**

The following RMOC recommendations were received and noted :

- RMOC Position Statement on the use of heparinised saline for maintaining patency of central venous catheters in adults  
<https://www.sps.nhs.uk/articles/maintaining-patency-of-central-venous-catheters-in-adults-rmoc-position-statement/>
- RMOC shared care survey
- RMOC APC mapping survey – this is being undertaken on behalf of NHS England to help map out the various local decision making committees that exist and what the variance is in respect of their Terms of Reference.

The North of Tyne, Gateshead and North Cumbria APC has been approached to act as one of the 'reference' APCs for the RMOC system. The committee agreed that engagement with this process would be beneficial as the role of

	<p>local decision making groups in terms of medicines optimisation and uptake in the economy is changing. This is in part due to the introduction of RMOCs and also in part due to the introduction of the voluntary scheme for branded medicines. The voluntary scheme for branded medicines pricing and access (voluntary scheme) is a non-contractual voluntary agreement between DHSC and ABPI that aims to provide stability and predictability for all parties in terms of the UK's branded medicines expenditure and the medicines pricing and access environment for the period 2019 to 2023. The voluntary scheme aims to achieve a balance between patient access, affordability and supporting the development of innovative new medicines, including support for small companies. As a result of this, NICE will play a larger role in the evaluation of these new medicines and there will be a reduced need for local evaluation of new medicines.</p>
<p><b>2019/26</b></p>	<p><b>Northern (NHS) Treatment Advisory Group (N-TAG )</b>  The following recommendation was finalised by NTAG at their meeting on 26/02/19 and is now available on the website:</p> <ul style="list-style-type: none"> <li>• <a href="#">i-Port Advance® for use in children and adults with Type 1 diabetes</a></li> </ul> <p>The formulary will reflect these recommendations.</p>
<p><b>2019/27</b></p>	<p><b>NICE Technology Appraisals</b>  The formulary will be amended to reflect the following:</p> <ul style="list-style-type: none"> <li>• TA555 : <a href="#">Regorafenib for previously treated advanced hepatocellular carcinoma</a></li> <li>• TA556 : <a href="#">Darvadstrocel for treating complex perianal fistulas in Crohn's disease</a></li> <li>• TA557 : <a href="#">Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic, non-squamous non-small-cell lung cancer</a></li> <li>• TA558 : <a href="#">Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease</a></li> <li>• TA559 : <a href="#">Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies</a></li> <li>• TA560 : Terminated appraisal <a href="#">Bevacizumab with carboplatin, gemcitabine and paclitaxel for treating the first recurrence of platinum-sensitive advanced ovarian cancer</a></li> <li>• TA561 : <a href="#">Venetoclax with rituximab for previously treated chronic lymphocytic leukaemia - Technology appraisal guidance</a></li> <li>• TA562 : <a href="#">Encorafenib with binimetinib for unresectable or metastatic BRAF V600 mutation-positive melanoma – technology appraisal guidance</a></li> <li>• TA563 : <a href="#">Abemaciclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer - technology appraisal guidance</a></li> <li>• TA564 : Terminated appraisal <a href="#">Dabrafenib with trametinib for treating advanced metastatic BRAF V600E mutation-positive non-small-cell lung cancer</a></li> <li>• TA565 : <a href="#">Benralizumab for treating severe eosinophilic asthma - guidance</a></li> <li>• TA567 : <a href="#">Tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic therapies (guidance)</a></li> <li>• TA465: <a href="#">Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma</a> The EMA have advised that no new people should start treatment with olaratumab and NHS England have</li> </ul>

	<p>confirmed that the Cancer Drugs Fund will not fund any new people. People taking olaratumab and appearing to benefit from it, should talk to their doctor about their continued treatment or other treatment options.</p> <ul style="list-style-type: none"> <li>• TA568 : Terminated appraisal <a href="#">Abatacept for treating psoriatic arthritis after DMARDs</a></li> <li>• TA569 <a href="#">Pertuzumab for adjuvant treatment of HER2-positive early stage breast cancer</a></li> <li>• TA570 <a href="#">Pembrolizumab for treating recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based chemotherapy (terminated appraisal)</a></li> <li>• TA571 <a href="#">Brigatinib for treating ALK-positive advanced non-small-cell lung cancer after crizotinib</a></li> <li>• TA 572 for Ertugliflozin as monotherapy or with metformin for treating type 2 diabetes <a href="https://www.nice.org.uk/guidance/ta572">https://www.nice.org.uk/guidance/ta572</a> (recommended through the fast track appraisal process therefore NHS England and commissioning groups have agreed to provide funding to implement this guidance 30 days after publication).</li> </ul>
<p><b>2019/28</b></p>	<p><b>NHS England</b>  <b>Flash Glucose Monitoring</b></p> <ul style="list-style-type: none"> <li>o National arrangements for funding of relevant diabetes patients</li> <li>o NTAG criteria Nov 2017</li> <li>o NTAG update from meeting on 27/3/19</li> </ul> <p>The APC endorse the NTAG position on the use of Flash Glucose monitoring and are aware that this guidance is currently under review to ensure it is in line with the new NHS England guidance. The required pathways for patient access and review need reconsidered as part of this update.</p> <p>The committee agreed that DC can take chair`s action to endorse the new NTAG guidance when it is published.</p> <p>The following NHS England communications were noted and will be reflected in the formulary:</p> <ul style="list-style-type: none"> <li>• SSC1958 - Clinical Commissioning Policy: Infliximab for Progressive Pulmonary Sarcoidosis in Adults</li> <li>• SSC1959 - Clinical Commissioning Policy: Gemcitabine and capecitabine following surgery for pancreatic cancer (all ages)</li> <li>• SSC1960 - EAMS – Atezolizumab, in combination with bevacizumab, paclitaxel and carboplatin, for the treatment of adult patients with EGFR</li> <li>• SSC1961 - Publication and implementation of new clinical commissioning policies and service specifications following November 2018 Prioritisation</li> <li>• SSC1962 - Abemaciclib with an aromatase inhibitor for untreated advanced hormone-receptor positive, HER2-negative breast cancer</li> <li>• SSC1963 - Venetoclax with rituximab for previously treated relapsed or refractory chronic lymphocytic leukaemia</li> <li>• SSC1964 - Encorafenib with binimetinib for unresectable or metastatic BRAF V600 mutation-positive melanoma</li> <li>• SSC1966 - EAMS – Dupilumab in the treatment of adolescent patients ≥12 to &lt;18 years of age with severe atopic dermatitis</li> <li>• SSC1968 - Tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma in adults after 2 or more systemic therapies</li> </ul>

	<ul style="list-style-type: none"> <li>• SSC1969 - NICE TA 542: Cabozantinib for untreated advanced renal cell carcinoma</li> <li>• SSC1970 - NICE TA 539: Lutetium (177Lu) oxodotreotide for treating unresectable or metastatic neuroendocrine tumours</li> <li>• SSC1971 - NICE FAD 544: Dabrafenib with trametinib for adjuvant treatment of resected BRAF V600 mutation-positive melanoma</li> <li>• SSC1974 - NICE TA 541: Inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia</li> <li>• SSC1975 - Revised Commissioning Criteria for the use of Immunoglobulins:</li> <li>• SSC1978 - NICE TA FAD: Brigatinib for treating ALK-positive advanced non-small-cell lung cancer after crizotinib</li> <li>• SSC1979 - NICE TA FAD: Pertuzumab for adjuvant treatment of HER2-positive early stage breast cancer</li> <li>• SSC1980 - NICE TA 545: Gemtuzumab ozogamicin for untreated acute myeloid leukaemia</li> <li>• SSC1981 - National procurement for tenofovir and emtricitabine (Truvada®) and Tenofovir, emtricitabine and efavirenz (Atripla®)</li> <li>• SSC1983 - CCP: Selective internal radiation therapy (SIRT) for the treatment of chemotherapy refractory or intolerant, unresectable primary intrahepatic cholangiocarcinoma (all ages)</li> </ul>
2019/29	<p><b>Chair's action</b> None</p>
2019/30	<p><b>Any other business</b></p> <ol style="list-style-type: none"> <li>1. Tinzaparin supply shortage. To help address national shortages NuTH have been asked to temporarily switch to use of enoxaparin for prophylaxis. ML will enquire if additional information can be included on discharge summaries to help primary care understand the changes. It was agreed the wording on the formulary entry will need to be updated to reflect the temporary change.</li> <li>2. Hospital initiated medicines and patient records. Concern was expressed that the increasing complexity of hospital prescribing, and routes of supply, can increase the potential for gaps in information recorded in patient notes both in primary and secondary care. This includes, but is not limited to Homecare supply of biologics for rheumatology, gastroenterology and dermatology. The introduction of the Great North Care Record should help address some of these issues but it was agreed that in the interim trust chief pharmacists have a role in influencing the development of their IT systems and discharge communications to ensure risk is minimised as far as possible.</li> <li>3. Brexit. The national advice with regards to stockpiling of medicines was noted and will be followed. Local action in respect of clinical trials has been taken. Trusts have a role to play in monitoring shortages as they arise and in supporting the provision of clinical advice where alternatives are needed and where SPS national advice is not in place.</li> </ol>
	<p><b>Date and time of next meeting(s)</b> Tuesday 9th July 2019 12:30 pm Tuesday 8th October 2019 12:30 pm</p>
	<p><b>Signed:</b> _____ <b>Date:</b> _____  (Chair of the APC)</p>