

**North of Tyne, Gateshead and North Cumbria Area Prescribing Committee
Minutes of a meeting held on
Tuesday 10th July 2018
at North Tyneside General Hospital**

Present:

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
Sue Dickinson	Director of Pharmacy	RDTC
Tim Donaldson	Chief Pharmacist/Associate Director of Medicines Management	NTW
Bill Glendinning	Clinical Director of Pharmacy	NCUHT
Matt Grove	Consultant Rheumatologist and Head of Service	NHCT
Ann Gunning		NoT LPC
Steve Llewellyn	Medicines Optimisation Pharmacist	NGCCG
Matthew Lowery	Formulary and Audit Pharmacist	NUTH
Frank McAulay	Associate Medical Director	GHFT
Neil Morris	Medical Director	NG CCG
Helen Seymour	Senior Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Susan Turner	Pharmacist	NECS
Hannah Willoughby	Pharmacist	NGCCG

Apologies

Nirmalan Arulanantham	Consultant physician and clinical pharmacologist	NCUHT
Pat Bottrill	Lay Representative	
Ruth Evans	Medical Director	NT CCG
Neil Gammack	Chief Pharmacist	GHFT
Tomal Karim		ST&G LPC
Andrea Loudon	Primary Care Development and Medicines Lead	NC CCG
Graham Syers	Prescribing Lead	N CCG
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
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

2018/39	Bill Glendinning, from North Cumbria University Hospitals Trust, was welcomed to the meeting. North Cumbria has formally joined the APC.
2018/40	Declarations of interest None.
2018/41	Appeals against previous decisions None.
2018/42	Minutes and decision summary from previous meeting. The following documents were accepted as a true record: <ul style="list-style-type: none"> • Decision summary from 10/04/18. • Minutes from 10/04/18.
2018/43	Matters arising not on the agenda or Action Log. None.
2018/44	Action Log The action log was reviewed and will be updated to reflect the following: <ul style="list-style-type: none"> • 2017/02 Audit of oral glycopyrronium bromide – agenda item. Remove from action log. • 2017/41 Povidone-iodine 0.35% sterile aqueous solution – 6 month data will be available at end of July therefore deadline extended to September. • 2017/56 APC Guideline on Prescribing PPIs – MGUG agenda item. Remove from action log. • 2017/56 Information leaflet for lidocaine patches – no longer required. Remove from action log. • 2018/07 - Rituximab approvals. 3 previous approvals, approved in 2006, are not currently covered by NICE /NHSE commissioning policies. Confirmation has been received that these indications are still recommended by the Haematology Regional Network and charges are currently accepted by NHS England. Remove from action log. • 2018/12 - Items which should not be routinely prescribed in primary care: Guidance for CCGs – Formulary updated. Action complete, remove from action log. • 2018/27 Corticosteroid foam enemas – action outstanding. • 2018/28 Items of limited clinical value – formulary updated. Progress on liothyronine, lidocaine and daily tadalafil discussed. <ul style="list-style-type: none"> ○ Lidocaine patch information leaflet – agreed this was not needed. The formulary reflects that use should only be in line with licensed indications. Remove from action log. ○ N-TAG has issued guidance on daily phosphodiesterase inhibitors and this has been communicated to clinicians. ○ A liothyronine patient letter, outlining the national guidance, is to be drafted by HS/SL/NM, shared with MGUG members for agreement, and endorsed by endocrinology specialists from all trusts. Referral in to secondary care would be accepted on an exceptional basis. TD raised the potential role of liothyronine in mental health. The use of liothyronine in resistant depression is not referred to in the national guidance. There is no formulary approval for this indication and therefore if the regional affective disorders unit feels there is a role for this indication an application should be submitted, potentially through N-TAG. • 2018/28 Conditions for which over the counter items should not routinely be prescribed in primary care. Member organisations are encouraged to

	<p>explore the implications of this guidance with all teams and departments, including walk in centres, A&E and community services, so that a whole economy approach is delivering consistent messages to patients in relation to self-care. Work is underway regionally to explore further stakeholders and required communications. These include, but are not limited to, local authorities for medicines policies in schools and care home implications.</p> <ul style="list-style-type: none"> • 2018/30 MGUG secretarial support – agenda item – remove from action log • 2018/33 Potential RMOC role in shared care advice. Request prepared ready for submission through the RMOC online submission process. Action complete.
<p>2018/45</p>	<p>Revised membership and Terms of Reference The Terms of Reference have been updated to reflect the new membership and to include the role of the APC in giving due consideration to RMOC recommendations.</p>
<p>2018/46</p>	<p>Report from the Formulary Sub-committee The formulary website is available at North of Tyne, Gateshead and North Cumbria Area Prescribing Committee Formulary.</p> <p>Minutes and recommendations from the North of Tyne, Gateshead and North Cumbria FSC meeting held on 24/5/18: 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:</p> <p>Methoxyflurane (Penthrox®)</p> <p>Concerns were raised by the anaesthetists on FSC relating to the risk of occupational exposure in nursing/ambulance staff resulting from unsupervised patients not using the device correctly. It was noted that there is widespread use in other countries and areas of the UK but it was still felt that constant supervision would be required during administration and that this would negate any savings in time from reducing the use of IV morphine. Further concerns were raised about patients receiving this in ED then going to theatre (e.g. for a fracture fixation) and being given sevoflurane. F McA asked if NEAS and A& E specialists had been involved in the application. This was unclear.</p> <p>The safety issues were raised further with the applicant after the meeting but assurances had not been enough to satisfy the committee.</p> <p>Post meeting note: John Wright, ED consultant at NUTH, has confirmed that he had discussed this application with NEAS.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Methoxyflurane (Penthrox®) Decision: Rejected</p> </div> <p>Desmopressin (Noqdirna®)</p> <p>Desmopressin 25 microgram & 50 microgram oral lyophilisate (Noqdirna®) has been requested for the treatment of nocturia due to idiopathic nocturnal polyuria in adults, including those over the age of 65. There are no other</p>

licenced treatments for idiopathic nocturnal polyuria. Current treatment options may include desmopressin 100 micrograms, although larger doses are associated with a higher risk of hyponatraemia. Desmopressin tablets are licenced for nocturnal enuresis in patients less than 65 years of age. The SMC and AWMSG have approved Noqdirna® but with restricted use in patients over 65 years only.

For the number of voids per night the difference between Noqdirna® and placebo was -0.22 in women and -0.37 in men. This is below that considered to be clinically important by Cochrane. Compared to placebo improvements in Quality of Life were seen but again these did not meet the thresholds considered to be clinically important by Cochrane. It was noted that desmopressin 100 microgram tablets have been on the formulary for a considerable time for nocturnal enuresis and licenced indications.

Desmopressin (Noqdirna®)

Decision: Rejected

Methylphenidate (Xaggitin XL®)

Methylphenidate XL 18mg 27mg 36mg and 54mg capsules (Xaggitin XL®) are licenced for the treatment ADHD in children aged 6 years of age and over.

Xaggitin XL® is bioequivalent to Concerta XL® but is 50% cheaper.

TD highlighted that there would be an opportunity cost in making this switch and that some thought needed to be given as to how this would be undertaken. The committee agreed that patients/carers would need reassurance around the equivalence of the 2 products before any changes were made.

Methylphenidate (Xaggitin XL®)

Decision: Approved

Methylphenidate (Xaggitin XL®) will be the first line formulary choice and Concerta XL® removed for new patients. Existing patients being prescribed Concerta XL® should be reviewed and switched as appropriate. The actions and costs associated with making this change will be given consideration by commissioners.

2018/47

Report from the Medicines Guidelines and Use Group

Draft minutes from meeting held on 25/6/18 were received and noted.

Revised MGUG terms of reference were discussed. Member organisations are expected to undertake a share of the workload and have a role in ensuring guidance is implemented. NGCCG agreed to continue providing secretarial support on this basis. It was recognised that wider representation including finance and commissioning representatives and the LMC would be beneficial. The role of AHSN and other clinical networks is also important to ensure there is no duplication of effort/contradiction of advice. The involvement of North Cumbria will have an impact on guideline review but it was agreed that this would be a gradual process as existing guidance was due for review. Key stakeholders from North Cumbria would need to be identified early on in guideline development to ensure a joint approach.

MGUG is reviewing the process for guideline development to ensure that only guidance that adds value/clarity is progressed. There should be no duplication with existing national guidance.

	<ul style="list-style-type: none"> • Guidelines approved: <ul style="list-style-type: none"> ○ Thyroid Regional Assessment and Management Plan ○ Bariatric Prescribing and Monitoring Guidance for GPs June 2018 – this document applies to the after care of patients undergoing bariatric surgery at Northumbria trust after discharge from the service. There may be some different expectations for patients who attend Sunderland and work will be undertaken to explore this. The guidance also applies to patients who have elected to have private surgery. They will be treated in line with NHS patients following discharge from their provider. ○ Blood Glucose monitoring – minor update to reflect product discontinuation. • Shared Care Guidelines approved: <ul style="list-style-type: none"> ○ Lithium shared care - updated guideline Cinacalcet in Primary Hyperparathyroidism – updated to reflect commissioning arrangements. NHSE now fund the treatment of all new patients who therefore should be receiving treatment from specialist centres only. For existing patients (pre Nov 2016) GPs may continue to prescribe using this shared care guideline. ○ Melatonin shared care - Children and Young People - update ○ Shared Care Guidance for the Monitoring of Tocilizumab in adult patients ○ Shared care guidance for the Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients aged 18 years and over. Previously there were individual share care guidance sheets for individual ADHD medications; these have now been merged to reflect national advice that states shared care documentation should be disease specific as far as possible. Branding, apart from that recommended in <u>Branded Prescribing – Medicines that are Not Suitable for Generic Prescribing – Apr 2016</u> , will be removed. Further discussion is required to explore if any changes can be made to monitoring responsibilities. Commissioners will need to progress this. ○ Shared care guidance for the Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents aged from 6 to 17 years – as above. ○ Giggie incontinence - methylphenidate shared care • Guidelines/information sheets for retirement <ul style="list-style-type: none"> ○ Melatonin information sheet – approved indications to be reflected in the formulary ○ Primary care guidance on prescribing PPIs ○ Denosumab information sheet – MGUG had suggested that the approved indications and secondary care initiation could be made clear in the formulary, negating the need for additional documentation. MG stated that he felt this was still required and would undertake the update.
<p>2018/48</p>	<p>Harrogate and Rural District CCG policy on branded prescribing The above draft policy was considered at the request of the regional prescribing forum. The document is broadly in line with the APC guidance on branded prescribing but goes further in recognising that prescribing some items using their brand name, where there is no clear and outstanding clinical case to do so, can sometimes reduce immediate costs to the CCG's drugs bill. This is not an approach recommended by the Department of Health or the</p>

	<p>PSNC as it may not reduce overall costs to the NHS but the committee recognised the current financial pressures all organisations face and understand that CCGs, by exception, may feel the need to consider the financial value of any such decision on a case by case basis. Any such consideration would include:</p> <ul style="list-style-type: none"> ○ the likely resulting change in market, such as other competitive products and price changes in the NHS Drug Tariff. ○ whether the NHS will incur additional expense by taking such an approach ○ the clinical risks and disruption to individual patients ○ the workload involved with change ○ features of the branded alternative, including equivalent in bioavailability and release profile ○ licensed indications ○ significant variance in excipients between the formulations ○ guarantee from the manufacturer of the immediate and long-term supply chain and its availability to all local dispensing contractors ○ whether the product is in Category M of the NHS Drug Tariff ○ the impact on local dispensing contractors <p>The current APC guidance on branded prescribing will be updated to include a statement to reflect this but the formulary will remain focused on generic prescribing unless there is a clinical reason to do differently.</p>
<p>2018/49</p>	<p>RMOC</p> <p>The following RMOC recommendations were received :</p> <ul style="list-style-type: none"> • Regional Medicines Optimisation Committee (North) has issued a recommendation on <u>standardising strengths of high risk, unlicensed oral liquids formulations for anti-TB medicines</u>. Standardised specifications of ethambutol 400mg/5mL, pyrazinamide 500mg/5mL and isoniazid 50mg/5mL have been proposed and will be submitted for addition to the British Pharmacopoeia and BNF-C. Prescribers are encouraged to restrict prescribing to these three products. The APC endorses these recommendations. • RMOC position statement on access to antidotes and rarely used medicines https://www.sps.nhs.uk/articles/regional-medicines-optimisation-committee-antidotes-and-rums-position-statement/. The APC notes these recommendations and encourages member trusts to support the work that is underway. • Regional Medicines Optimisation Committee Briefing: Best Value Biologicals: Adalimumab Update 1 https://www.sps.nhs.uk/articles/rmoc-briefing-paper-on-adalimumab/ The purpose of this briefing is to provide an update for provider trusts and commissioners which summarises: <ul style="list-style-type: none"> ○ Advice on the next steps for commissioners and providers; ○ NHS England's position on biosimilar adalimumab; ○ Progress to date in planning for the patent expiry of the originator adalimumab product Humira® in October 2018; ○ Further information on biosimilars. • Regional Medicines Optimisation Committee Briefing: Best Value Biologicals: Adalimumab Update 2 www.sps.nhs.uk/articles/rmoc-briefing-paper-on-adalimumab-no-2/ .

	<p>The committee noted a second RMOC briefing paper on adalimumab. It forms the May edition of an expected monthly series of briefings on best value biological medicines. The briefing summarises:</p> <ul style="list-style-type: none"> ○ advice on next steps for commissioners and providers; ○ practical advice in the context of homecare services; and ○ progress to date in planning for the patent expiry of the originator adalimumab product Humira® in October 2018. ○ In addition, a clinical briefing sheet and an adalimumab homecare patient record form are provided. <p>The APC received and noted both these publications and await further information.</p> <ul style="list-style-type: none"> • RMOC Midlands & East meeting summary – April https://www.sps.nhs.uk/articles/regional-medicines-optimisation-committee-update/ The APC received and noted this summary. There will be a need for any work on homely medicines in care homes to link with the national self-care agenda. • Insulin preparations: RMOC recommendations of safety considerations for formulary decision making <u>Insulin preparations: RMOC recommendations of safety considerations for formulary decision making</u> The APC received and noted these recommendations.
<p>2018/50</p>	<p>Northern (NHS) Treatment Advisory Group (N-TAG) The June meeting was cancelled.</p>
<p>2018/51</p>	<p>NICE Technology Appraisals The formulary will be amended to reflect the following:</p> <ul style="list-style-type: none"> • TA517 : Avelumab for treating metastatic Merkel cell carcinoma • TA518 : Tocilizumab for treating giant cell arteritis • TA519 : Pembrolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy • TA520 : Atezolizumab for treating locally advanced or metastatic non-small-cell lung cancer after chemotherapy • TA521 : Guselkumab for treating moderate to severe plaque psoriasis • TA522 : Pembrolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable • TA523 : Midostaurin for untreated acute myeloid leukaemia • TA524 : Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma • TA525 : Atezolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy • TA526 : Arsenic trioxide for treating acute promyelocytic leukaemia • TA217 : Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (minor update) <p>IC highlighted the publication of the NICE FAD for dupilumab. There are significant numbers of patients expected to start treatment on this once the TAG is published and commissioners need to be aware of the cost pressures. Initial indications from NUTH are that they may have 200 patients who will meet the criteria for treatment.</p>
<p>2018/52</p>	<p>NHS England</p> <p>The following NHS England communications were noted and will be reflected in the formulary:</p> <ul style="list-style-type: none"> • SSC1853 - NICE Technology Appraisal 500: Ceritinib for untreated ALK-

	<p>positive non-small-cell lung cancer</p> <ul style="list-style-type: none"> • SSC1854 - Immediate Anti-Retroviral Therapy Treatment Policy • SSC1857 - NICE Technology Appraisal Final Appraisal Determination: Atezolizumab for treating locally advanced or metastatic non-small-cell lung cancer after chemotherapy • SSC1859 - NICE Technology Appraisal 498: Lenvatinib with everolimus for previously treated advanced renal cell carcinoma • SSC1860 - NICE TA FAD: Pembrolizumab for untreated locally advanced or metastatic urothelial carcinoma in adults when cisplatin-containing chemotherapy is unsuitable • SSC1861 - NICE Technology Appraisal 502: Ibrutinib for treating relapsed or refractory mantle cell lymphoma • SSC1862 - NICE Technology Appraisal Final Appraisal Determination: arsenic trioxide for treating acute promyelocytic leukaemia • SSC1863 - NICE Technology Appraisal Final Appraisal Determination: Midostaurin for treating adults with newly diagnosed acute FLT3-mutation-positive myeloid leukaemia • SSC1864 - NICE Technology Appraisal Final Appraisal Determination: brentuximab vedotin for treating CD30-positive Hodgkin lymphoma in adults with relapsed or refractory disease • SSC1865 - Rituximab for second line treatment for anti-NMDAR autoimmune encephalitis (all ages) • SSC1870 - NICE Technology Appraisal Final Appraisal Determination: Atezolizumab for treating locally advanced or metastatic urothelial carcinoma in adults who have had platinum-containing chemotherapy • SSC1872 - Nivolumab: Update to Summary of Product Characteristics • SSC1873 - NICE TA FAD: Crizotinib for treating ROS1-positive advanced non-small-cell lung cancer • SSC1874 - NICE TA FAD: Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer • SSC1875 - NICE Technology Appraisal 509: Pertuzumab with trastuzumab and docetaxel for treating HER2-positive breast cancer • SSC1878 - National Framework Agreement for Human Immunoglobulins • SSC1879 - NICE TA FAD: Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer (CDF review of TA447) • Specialised Commissioning Spring briefing
<p>2018/53</p>	<p>Chair's action None</p>
<p>2018/54</p>	<p>Any other business Opioids and pain management DC informed the committee that he had been approached, and agreed, to pull together a group of interested colleagues to try and co-ordinate varying strands of work that are beginning to emerge in relation to opioid use in chronic pain as well as other medication use in the context of pain management. This would initially have a prescribing focus but the implications extend to commissioning in terms of services for non-drug management. It was agreed that this would initially remain at a North of Tyne and Gateshead geography but that he would approach Public Health England to see if this could be co-ordinated with work they are currently scoping.</p>
	<p>Date and time of next meeting(s)</p>

Tuesday 9th October 2018 12:30 pm
Conference room 2
Walkergate Park Hospital
4 Benfield Rd
Newcastle upon Tyne
NE6 4QD
Tuesday 8th January 2019 12:30 pm
Conference room 2
Walkergate Park Hospital
4 Benfield Rd
Newcastle upon Tyne
NE6 4QD
Tuesday 2nd April 2019 12:30 pm
Conference room 2
Walkergate Park Hospital
4 Benfield Rd
Newcastle upon Tyne
NE6 4QD
Tuesday 9th July 2019 12:30 pm
Rooms 4 & 5
Education Centre
Wansbeck General Hospital
Tuesday 8th October 2019 12:30 pm
Conference room 2
Walkergate Park Hospital
4 Benfield Rd
Newcastle upon Tyne
NE6 4QD

 Signed:

Date:

9/11/18

(Chair of the APC)

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 10th July 2018**.

Classification of products:

R = 'RED' drugs for hospital use only


A = 'AMBER' drugs suitable for use under Shared Care arrangements

GP = '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				
Methoxyflurane (Pentrox®)		✓		<p>Pentrox was discussed at the FSC in November 2016 where it was decided to defer the application until the Public Assessment Report (PAR) was published and the MHRA commentary on the safety issues (renal impairment) could be reviewed. The PAR states a safety study was planned and that the manufacturer had provided risk management materials. Despite this it was felt an age cut-off would be appropriate due to the risk of undiagnosed renal impairment in older patients. Significant concerns were also raised regarding the risk of occupational exposure, and toxicity in patients who were subsequently transferred to theatre (e.g. for fracture fixation) who were then given sevoflurane. It was felt that any savings in nursing time would be negated if IV morphine was subsequently required.</p> <p>Decision: The request for Pentrox was rejected on the grounds of safety.</p>
2) New Requests				
Potassium Citrate MR Tablets (Urocit®-K)		✓		<p>Urocit®-K has been requested for the treatment of hypocitraturia and recurrent kidney stone formation for a cohort of patients who cannot tolerate the UK licensed preparations of potassium citrate. Affected patients are seen in a specialist renal clinic. A previous application was rejected due to concerns over cost effectiveness. The cost has reduced significantly, although still expensive. There is a lack of comparative data and it is not clear if Urocit®-K was the actual formulation used in studies.</p> <p>Decision: The request for Urocit®-K was rejected on the basis that it isn't deemed cost-effective and the evidence of its efficacy is unconvincing.</p>

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
3) New formulations & extensions to use				
Levonorgestrel 19.5mg IUD (Kyleena®)	✓ G			<p>Levonorgestrel 19.5mg intrauterine system is a long acting contraceptive lasting 5 years. The contraceptive effectiveness, side-effect and adverse event profile of Kyleena® is similar to that of other LNG-IUDs.</p> <p>Kyleena® has the lowest cost per year of the currently available LNG-IUDs. It has been requested that Kyleena® is available in addition to Jaydess® and Mirena®. A treatment algorithm has been produced for LNG-IUDs.</p> <p>Decision: The request for Levonorgestrel 19.5mg IUD (Kyleena®) was approved</p>
Chondroitin bladder instillation (Gepan instill®)	✓ R			<p>Chondroitin-sulphate (Gepan® instill) has been requested as it is the only GAG replenishment treatment licensed (as a medical device) for interstitial cystitis/painful bladder syndrome, radiation cystitis, recurring bacterial cystitis and overactive bladder. As a medical device the standard of evidence is lower than that required for a medicine. There are no head to head studies with Cystistat® or Ialuril® however the evidence suggests Gepan® improves symptoms of interstitial cystitis, painful bladder syndrome, OAB, radiation cystitis and recurring bacterial cystitis. Patients could be taught to self-catheterise and administer Gepan® instill at home.</p> <p>Decision: The request for Chondroitin bladder instillation (Gepan instill®) was approved</p>
Desmopressin (Noqdirna®)		✓		<p>Desmopressin 25 microgram & 50 microgram oral lyophilisate (Noqdirna®) has been requested for the treatment of nocturia due to idiopathic nocturnal polyuria in adults. There are no other licenced treatments for idiopathic nocturnal polyuria. Current options for treatment may include desmopressin 100 micrograms tablets, which are licensed for nocturnal enuresis in patients less than 65 years of age, but these have a greater risk of hyponatraemia. Studies found that the difference in the number of voids per night between Noqdirna® and placebo were not clinically significant. This was also the case for quality of life improvements.</p> <p>Decision: The request for desmopressin 25 microgram & 50 microgram oral lyophilisate (Noqdirna®) was rejected.</p>

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Methylphenidate (Xaggitin XL®)	✓ 			<p>Methylphenidate XL 18mg, 27mg, 36mg and 54mg capsules (Xaggitin XL®) are licensed for the treatment ADHD in children aged 6 years of age and over. Xaggitin XL® is bioequivalent to Concerta XL® but is 50% cheaper. It has been requested for the same indications as Concerta XL®. Its use, including switching existing Concerta XL® patients, could lead to significant savings across the North of Tyne and Gateshead APC CCGs.</p> <p>Decision: The request for Methylphenidate (Xaggitin XL®) was approved. Existing patients being prescribed Concerta XL® should be reviewed and switched as appropriate.</p>
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC1853 - NICE Technology Appraisal 500: Ceritinib for untreated ALK-positive non-small-cell lung cancer				The formulary will reflect the NHS England position
SSC1854 - Immediate Anti-Retroviral Therapy Treatment Policy				The formulary will reflect the NHS England position
SSC1857 - NICE Technology Appraisal Final Appraisal Determination: Atezolizumab for treating locally advanced or metastatic non-small-cell lung cancer after chemotherapy				The formulary will reflect the NHS England position
SSC1859 - NICE Technology Appraisal 498: Lenvatinib with everolimus for previously treated advanced renal cell carcinoma				The formulary will reflect the NHS England position
SSC1860 - NICE TA FAD: Pembrolizumab for untreated locally advanced or metastatic urothelial carcinoma in adults when cisplatin-containing chemotherapy is unsuitable				The formulary will reflect the NHS England position
SSC1861 - NICE Technology Appraisal 502: Ibrutinib for treating relapsed or refractory mantle cell lymphoma				The formulary will reflect the NHS England position
SSC1862 - NICE Technology Appraisal Final Appraisal Determination: arsenic trioxide for treating acute promyelocytic leukaemia				The formulary will reflect the NHS England position
SSC1863 - NICE Technology Appraisal Final Appraisal Determination: Midostaurin for treating adults with newly diagnosed acute FLT3-mutation-positive myeloid leukaemia				The formulary will reflect the NHS England position
SSC1864 - NICE Technology Appraisal Final Appraisal Determination: brentuximab vedotin for treating CD30-positive Hodgkin lymphoma in adults with relapsed or refractory disease				The formulary will reflect the NHS England position
SSC1865 - Rituximab for second line treatment for anti-NMDAR auto-immune encephalitis (all ages)				The formulary will reflect the NHS England position
SSC1870 - NICE Technology Appraisal Final Appraisal Determination: Atezolizumab for treating locally advanced or metastatic urothelial carcinoma in adults who have had platinum-containing chemotherapy				The formulary will reflect the NHS England position
SSC1872 - Nivolumab: Update to Summary of Product Characteristics				The formulary will reflect the NHS England position
SSC1873 - NICE TA FAD: Crizotinib for treating ROS1-positive advanced non-small-cell lung cancer				The formulary will reflect the NHS England position
SSC1874 - NICE TA FAD: Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer				The formulary will reflect the NHS England position

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
SSC1875 - NICE Technology Appraisal 509: Pertuzumab with trastuzumab and docetaxel for treating HER2-positive breast cancer				The formulary will reflect the NHS England position
SSC1878 - National Framework Agreement for Human Immunoglobulins				The formulary will reflect the NHS England position
SSC1879 - NICE TA FAD: Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer (CDF review of TA447)				The formulary will reflect the NHS England position
5) Products considered by NICE				
TA517 : Avelumab for treating metastatic Merkel cell carcinoma				The formulary will reflect the NICE TAG
TA518 : Tocilizumab for treating giant cell arteritis				The formulary will reflect the NICE TAG
TA519 : Pembrolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy				The formulary will reflect the NICE TAG
TA520 : Atezolizumab for treating locally advanced or metastatic non-small-cell lung cancer after chemotherapy				The formulary will reflect the NICE TAG
TA521 : Guselkumab for treating moderate to severe plaque psoriasis				The formulary will reflect the NICE TAG
TA522 : Pembrolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable				The formulary will reflect the NICE TAG
TA523 : Midostaurin for untreated acute myeloid leukaemia				The formulary will reflect the NICE TAG
TA524 : Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma				The formulary will reflect the NICE TAG
TA525 : Atezolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy				The formulary will reflect the NICE TAG
TA526 : Arsenic trioxide for treating acute promyelocytic leukaemia				The formulary will reflect the NICE TAG
TA217 : Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (minor update)				The formulary will reflect the NICE TAG
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
No meeting				
7) Appeals against earlier decisions by the APC				
None				
8) Miscellaneous decisions by the APC				
Octreotide – palliative care	<p>Octreotide preparations are currently on formulary for acromegaly and neuroendocrine tumours as Red drugs. They were initially funded by primary care, but the status changed to Red when they became commissioned by NHS England. Octreotide is also used in end of life care to manage excessive GI secretions (as endorsed by the NECN palliative care guideline) but the RED status has caused access problems for patients in the community. The use in end of life care is to be added to the formulary as a green plus indication.</p> <p>Decision: The committee agreed to endorse the use of octreotide for managing excessive GI secretions in end of life care. This indication will have a Green Plus status. The information leaflets should be updated accordingly.</p>			

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Glycopyrronium 1mg/5ml MND - review				<p>Following an appeal heard on 10th January 2017, the North of Tyne and Gateshead Area Prescribing Committee allowed the limited use of glycopyrronium suspension 1mg/5ml for the treatment of distressing sialorrhoea in patients with motor neurone disease (MND) subject to a review of such use being undertaken in 12 months' time. Glycopyrronium suspension 1mg/5ml was approved in the following circumstances:</p> <ul style="list-style-type: none"> • First line use in patients with MND with cognitive impairment. • Second line use in patients who had failed other treatment options such as hyoscine patches or who had intolerance to other agents. <p>The review has now been carried out which gives some assurances and shows the overall cost is less than originally estimated due to lower dosages being used. It was noted in some cases glycopyrronium was used as a first line treatment outside of the original approval.</p> <p>Decision: The committee are happy to recommend the continued inclusion of glycopyrronium 1mg/5ml for the treatment of sialorrhoea in MND patients provided the usage continues to be restricted and guidance is followed in relation to its initiation.</p>
Formulary Review				<p>Chapter 4 – Recommendations:</p> <p>A review of chapter 4 was undertaken to ensure formulations and approvals are all still valid.</p> <p>Diazepam 10mg injection was removed from rapid tranquilisation guidance as this does not appear in NICE guidance.</p> <p>Piportil depot to be removed to reflect product discontinuation.</p> <p>Fluphenazine – annotation to be added to reflect product discontinuation in late 2018.</p> <p>A suggestion to include escitalopram was rejected – it was noted that the NICE recommendation for social anxiety disorder (CG159) was for escitalopram or sertraline. The committee felt an official application should be submitted if this is wanted in addition to sertraline for this indication.</p> <p>Other actions agreed and formulary to be updated.</p>

