North of Tyne, Gateshead and North Cumbria Area Prescribing Committee

Minutes of the meeting held on Tuesday 8th October 2019 Cobalt Business Park

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
Sarah Chandler	Formulary Pharmacist	NHCT
Tim Donaldson	Chief Pharmacist/Controlled Drugs Accountable Officer	CNTW
Paul Fieldhouse	Clinical Director of Pharmacy	NCICFT
Matt Grove	Consultant Rheumatologist	NHCT
Paul Conroy		NoT LPC
Naeem Iqbal	Prescribing Lead	NTCCG
Steve Llewellyn	Medicines Optimisation Pharmacist	NGCCG
Matthew Lowery	Formulary and Audit Pharmacist	NUTH
Frank McAulay	Associate Medical Director	GHFT
Graham Syers	Clinical Director of Primary Care	N CCG
Sheetal Sundeep	Consultant Microbiologist	NHCT
Susan Turner	Pharmacist	NECS
Hannah Willoughby	Pharmacist	NGCCG

Apologies

Sue Dickinson	Director of Pharmacy	RDTC
Neil Gammack	Chief Pharmacist	GHFT
Helen Seymour	Senior Pharmacist	NECS
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
CNTW	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

2019/48	**Declarations of interest** None
2019/49	**Appeals against previous decisions** None
2019/50	**Minutes and decision summary from previous meeting.** The following documents were accepted as a true record: • Decision summary from 9/7/19. • Minutes from 9/7/19.
2019/51	**Matters arising not on the agenda or Action Log.** None
2019/52	**Action Log** The action log was reviewed and will be updated to reflect the following: • 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. This report has now been received. It was agreed that IV lidocaine could continue to be used for post-operative pain but a further report of adverse events should be submitted to FSC after 12 months. Existing action closed. New action to be raised. • 2018/61 Catheter formulary task and finish group. Jackie Rees, a nurse consultant at NUTH and community specialist nurse Jill Dimopoulos from NHCFT are the nominated leads for this work. SL agreed to check progress and encourage resolution by end Dec for APC approval in January. • 2019/23 Citric acid – cough reflex testing. ML to chase. • 2019/25 Items which should not routinely be prescribed in primary care. Formulary amendments currently being made. Completion for end Dec 2019. Concern has been expressed by specialists on the inclusion of a price limit for needles as this potentially excludes safety needles required for healthcare staff administering injections to patients. Further clarification needed. • 2019/26 Vitamin D guidance. Agenda item. Remove from action log. • 2019/27 Primary management of drug prescribing in non-malignant pain. The RMOCs were asked if they would be considering national guidance which would remove the need for updating the APC local guideline on pain management. Feedback clarified that the RMOC system could potentially consider the need for some MO support in this area if a formal request was submitted but would not be reviewing the clinical evidence as NICE is currently developing two guidelines: o a guideline on chronic pain: assessment and management (estimated publication August 2020). o a guideline on safe prescribing and withdrawal management of prescribed drugs associated with dependence and withdrawal (estimated publication November 2021). The committee decided to wait on NICE guidance and continue local work through the APC pain subgroup. Implementation of current best practice is key. Action closed.

2019/53	**Report from the Formulary Sub-committee** The formulary website is available at North of Tyne, Gateshead and North Cumbria Area Prescribing Committee Formulary. Election of future Chair: Simon Thomas has resigned from his role as chair of the formulary subcommittee. Matthew Grove will replace him in this role. The committee thanked Simon for his invaluable contribution to the committee over many years and look forward to continuing to work with him as a member of the APC. **Minutes and recommendations from the North of Tyne, Gateshead and North Cumbria FSC meeting held on 2/9/19:** 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: **Buprenorphine oral lyophilisate (Espranor®)** Espranor® has been requested by the Chief Pharmacist from Change, Grow, Live, which is an organisation subcontracted by the local health authority to provide substance misuse services in Gateshead. It was recognised that there had been a recent price increase in sublingual buprenorphine and concerns were raised that this request was potentially being driven by a rebate scheme as the list price is very similar to the other sublingual buprenorphine preparations. There was not consistent support for the use of this product across the APC footprint. Concerns were expressed around patient safety implications including potential variation in bioavailability, confusion arising from multiple dosage forms of buprenorphine and the impact on community pharmacy supervised services. It was felt that the more rapid dissolution may be helpful however no evidence was presented that diversion was reduced. **Decision: Buprenorphine oral lyophilisate (Espranor®) Refused** **Progesterone 25mg SC/IM Injection (Lubion®)** Progesterone 25mg SC/IM Injection (Lubion®) has been requested by the Newcastle Fertility Centre for luteal support, in addition to vaginal progesterone, for frozen embryo transfer (FET) cycles in women who've experienced a prior biochemical pregnancy loss in a FET cycle. In fresh embryo cycles Lubion® is non-inferior to progesterone vaginal gel / pessaries. In frozen blastocyst transfer cycles a combination of IM oily progesterone plus progesterone pessaries or IM oily progesterone was more effective than vaginal progesterone alone for luteal support, leading to a significantly higher ongoing pregnancy rate. A different progesterone preparation was used in this study, but the exposure would be similar given the proposed dose of Lubion®. Concerns were raised regarding the generalisability of the results but it was recognised that the Newcastle Fertility Centre continually monitor their outcomes. The applicant has confirmed (post FSC) that women are allowed 3 egg collections cycles on the NHS and that the majority women don't have any eggs left over for subsequent frozen cycles.

	Decision: The committee agreed that Lubion® would be added to the formulary for luteal support in patients who've had a previous failed biochemical pregnancy in a FET cycle. This is subject to a report of outcomes after 40 patients. **Melatonin** Several new licensed preparations of melatonin are now available, including: • Slenyto® 1mg and 5mg tablets – licensed for insomnia in children and adolescents aged 2 - 18 with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient. • Melatonin 1mg/ml solution – licensed for the short-term treatment of jet-lag in adults. The committee accepts the current position of the off label use of Circadian® , and the use of unlicensed liquid, until a full formal review of melatonin products is undertaken in relation to short and long term safety issues, efficacy and costs. This will be progressed through the formulary subcommittee at the December meeting. **Dressings formulary update** The recommendations of a working group of specialist nurses were accepted and will be reflected in the formulary. It was acknowledged that the review group has not managed to meet as often as required due to capacity issues. ST agreed to approach NECS colleagues for associated administrative support to the group. FMcA agreed to approach a senior Gateshead nursing colleague to help facilitate/lead future work, noting that nursing leads in each locality would need to be identified to link in with APC work when needed. DC stated he is happy to make contact to explain this role once the contacts are identified. **Inhaler review** Olodaterol 2.5mcg /tiotropium 2.5mcg inhaler (Spiolto Respimat®) has been recommend by the inhaler review group as an option for COPD patients who require LABA/LAMA therapy but who are unable to use the dry powder LABA/LAMA inhalers on formulary. **Decision: approved as above.**
2019/54	**Report from the Medicines Guidelines and Use Group** Draft minutes from meeting held on 2/9/19 were received and noted. • Guidelines approved: o Prescribing trans anal irrigation o COPD guideline – after discussion it was agreed to progress as a consensus guideline; approved subject to completion of final formatting changes, and receipt of confirmation from NUTH respiratory clinicians that they are happy to endorse this guideline as such. o Cognitive enhancing medications - new guidance to replace existing

	▪ Acetylcholinesterase leaflet for primary care – Dec 17 ▪ Memantine information for primary care – Dec 17 ○ Blood glucose guideline - update ○ Non-valvular AF in primary care management - update ○ Antipsychotic leaflet - update ○ ADHD SCG Adults - update ○ ADHD SCG Children - update ○ Vitamin D guidance - approved subject to minor grammatical change • Guidelines/information sheets for retirement ○ Acetylcholinesterase leaflet for primary care – Dec 17 ○ Memantine information for primary care – Dec 17 The group had considered the RMOC guidance on liothyronine and feel that the current APC guidance is still appropriate. HW outlined some concerns relating to MGUG. The group is not functioning as well as it should be due to various factors not within the group's control. These include: • Volume of work • Scope of work – this is becoming wider and wider, often with limited reference to medicines • Review process for old guidelines is not clear – often falls to the originating author and therefore there can be a gap if this person has left their post. • Lack of engagement and accountability • Lack of senior clinician involvement. This discussion continued into agenda item 2019/55.
2019/55	**ICS Guidelines project** Drs. Helen Ryan, Catherine Lewis, & Tom Zamoyski, Guidelines Project GP Leads on behalf of the AHSN NENC and ICS Digital work stream, joined the meeting to give an update on their progress. The core aim of the project is to provide rapid access to locally relevant up-to-date clinical information created on an ICS footprint. The intention is to create/streamline the process at ICP level and then scale to ICS level once benefit is proven. There are 4 main pieces of work involved: • Promote core principle of collaboration & reducing duplication across ICP: ○ gauge appetite, identify barriers, define current 'creators' of content and index & map out current content • Optimise & adapt existing technology (TeamNet) ○ Single TeamNet Portal for the North ICP ○ to enable information sharing and collaboration at scale ○ Deliver value to GPs/organisations early – whilst longer term governance process in motion • Define Standards ○ For adding and storing guidelines and resources ○ to reduce variation & promote quick searching/accessing of content. • Formation of ICP Governance Group

	○ Admin resource for library maintenance ○ Analyse current resources in region, identify duplication, combine where possible and oversee creation of any new content at ICP level initially and eventually ICS level. The team informed the APC that there is recognition by Northumberland, North Tyneside and Newcastle Gateshead CCGs that collaboration and sharing is important. There are understandable concerns around potential disruption during any changeover period. Engagement with FTs is at an early stage. The team expressed a desire to utilise the APC's experience and expertise around governance and guideline development. Potential roles of the ICP governance group include: • Overall clinical responsibility for central portal content and quality assurance • Administrative resource for library item maintenance • Analysis of current resources at ICP level to identify duplication (combine content on ICP footprint if possible); identify content gaps, identify content due/overdue for review or updating (liaise with content creators where needed) • Commission/oversee creation of new content • Standardise scope of content included in central portal e.g. patient information/additional resources outwith clinical guidelines • Identify other/new regional/national guidance or content appropriate for central portal • Liaison with other groups e.g. FTs/clinical leads to promote use of central portal The APC applaud the ambition but stressed that they are not the forum for oversight of all guideline governance. They would be keen to link in with a larger ICP governance process however, retaining oversight and governance processes for the formulary and the medicines related content of any guidance that is being developed. It was acknowledged that the resource to translate this ambition into reality would be a challenge and needed further exploration. It was noted that North Cumbria are a member of our APC and do not fit the ICP footprint. They are currently looking at Canterbury pathways. The team was asked if the role of NTAG had been considered. This will be explored further.
2019/56	**Opiate/pain management sub-group** • Minutes for Opiate/pain management meeting held on 31.7.19 were received • Data to Qtr. 1 19/20 is showing some encouraging trends although it was accepted that this is multifactorial. The group meet again in November and it was agreed that although this was initially a task and finish group there is a need for it to continue, encompassing the Public Health England report on prescribed medicines. **Public health England prescribed medicines review** – received as above. https://www.gov.uk/government/publications/prescribed-medicines-review-report?utm_source=f7539fbc-14d9-4b84-a23c-5356aa152d47&utm_medium=email&utm_campaign=govuk-

	notifications&utm_content=immediate
2019/57	**RMOC** The following RMOC recommendations were received : • Updated RMOC guidance on liothyronine - reviewed by MGUG https://www.sps.nhs.uk/articles/updated-rmoc-guidance-prescribing-of-liothyronine/ • Regional Medicines Optimisation Committee Briefing: Best Value Biologicals: Adalimumab Update 6 https://www.sps.nhs.uk/wp-content/uploads/2019/07/Adalimumab-RMOC-Briefing-6.pdf • RMOC meeting update: newsletter 6 https://www.sps.nhs.uk/articles/regional-medicines-optimisation-committee-newsletter-issue-6-2019/
2019/58	**Northern (NHS) Treatment Advisory Group (N-TAG)** http://ntag.nhs.uk/ • Andexanet alfa (Ondexxya®), Factor Xa inhibitor antidote. • Patiromer (as patiromer sorbitex calcium) for the treatment of hyperkalaemia in adults. • Work plan The above recommendations were noted and will be reflected in the formulary.
2019/59	**NICE Technology Appraisals** The formulary will be amended to reflect the following: • TA588 Nusinersen for treating spinal muscular atrophy • TA589 Blinatumomab for treating acute lymphoblastic leukaemia in remission with minimal residual disease activity • TA590 Fluocinolone acetonide intravitreal implant for treating recurrent non-infectious uvetitis • TA591 Letermovir for preventing cytomegalovirus disease after a stem cell transplant • TA592 Cemiplimab for treating metastatic or locally advanced cutaneous squamous cell carcinoma • TA593 Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer • TA594 Brentuximab vedotin for untreated advanced Hodgkin lymphoma Terminated appraisal • TA595 Dacomitinib for untreated EGFR mutation-positive non-small-cell lung cancer • TA596 Risankizumab for treating moderate to severe plaque psoriasis • TA597 Dapagliflozin with insulin for treating type 1 diabetes • TA598 Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy • TA599 Sodium zirconium cyclosilicate for treating hyperkalaemia • TA600 Pembrolizumab with carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer • TA601 Bezlotoxumab for preventing recurrent Clostridium difficile infection (terminated appraisal) • TA602 Pomalidomide with bortezomib and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal) • TA603 Lenalidomide with bortezomib and dexamethasone for untreated multiple myeloma (terminated appraisal)

	• HST10 Patisiran for treating hereditary transthyretin amyloidosis
2019/60	**NHS England** The following NHS England communications were noted and will be reflected in the formulary: • SSC2034 - NICE TA 569: Pertuzumab for adjuvant treatment of HER2-positive early stage breast cancer • SSC2036 - Approval for use for immunoglobulin (Ig) for indications that currently fall into the grey or black categories in Clinical Guidelines for Immunoglobulin use • SSC2038 - NICE TA FAD: Cemiplimab for treating metastatic or locally advanced cutaneous squamous cell carcinoma • SSC2040 - Nusinersen for treating spinal muscular atrophy Type 1 • SSC2041 - NICE TA FAD: Dacomitinib for untreated EGFR-positive non-small-cell lung cancer • SSC2042 - NICE TA: Atezolizumab in combination for treating metastatic non-squamous non-small-cell lung cancer • SSC2045 - Withdrawal of Marketing Authorisation for olaratumab (Lartruvo®) • SSC2047 - NICE TA FAD: Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer • SSC2048 - NICE Highly Specialised Technology HST9: Inotersen for treating hereditary transthyretin amyloidosis • SSC2049 - NICE TA 563: Abemaciclib with an aromatase inhibitor for untreated advanced hormone-receptor positive, HER2-negative, locally advanced or metastatic breast cancer • SSC2051 - Cholic acid and chenodeoxycholic acid for treating inborn errors of bile acid synthesis • SSC2054 - Avelumab in combination with axitinib for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC) • SSC2056 - CCP: Sapropterin for Phenylketonuria (all ages) • SSC2058 - NICE TA: Brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma. • SSC2059 - CCP: Treatment for defined patients with multidrug-resistant tuberculosis (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB) including bedaquiline and delamanid • SSC2064 - NICE TA FAD: Olaparib tablets for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy • SSC2066 - Maternal intravenous immunoglobulin administration for prevention of alloimmune fetal and neonatal haemochromatosis • SSC2069 - NICE TA, Appraisal Consultation Document: Neratinib for extended adjuvant treatment of hormone receptor-positive, HER2-positive early stage breast cancer after adjuvant trastuzumab • SSC2070 - NICE TA FAD: Pembrolizumab with carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer • SSC2073 - Hepatitis B Vacc of patients with Chronic Kidney Disease • SSC2079 - NICE Highly Specialised Technology HST10: Patisiran for treating hereditary transthyretin amyloidosis

	• SSC2082 - EAMS: Dupilumab in the treatment of adolescent patients ≥12 to <18 years of age with severe atopic dermatitis who have responded inadequately to at least one systemic therapy or where the available systemic therapies
2019/61	**Chair's action** None
2019/62	**Any other business** **1. National Confidential Inquiry into Suicide and Safety in Mental Health self-audit toolkit.** TD informed the committee that work is underway within CNTW to complete the National Confidential Inquiry into Suicide and Safety in Mental Health self-audit toolkit. The NCISH report is specifically referenced with the NICE Key therapeutic topic [KTT24] 'Suicide prevention: optimising medicines and reducing access to medicines as a means of suicide' https://www.nice.org.uk/advice/ktt24 The report includes the attached section on prescribing, making specific reference to there being: *" a standard procedure in place in primary care and accident and emergency departments for safer prescribing of opiate analgesics and tricyclic antidepressants, which takes into account the toxicity of these drugs in overdose by:* *(i) Considering reduced, short-term supplies;* *(ii) Asking about supplies of over-the-counter opiate-containing medications kept at home or prescribed to someone else in the household;* *(iii) Ensuring patients newly prescribed antidepressants are aware of the time taken to work."* The APC member organisations have a responsibility to receive this review and take any recommendations through their appropriate governance processes and implement any subsequent changes into their clinical practice. **2.Medicines shortages** PB raised patient concerns over the current shortages of medicines and the impact on patient care. Concerns were acknowledged but it was agreed that this is a multifactorial issue including international supply issues, the value of the pound and fears over a no deal Brexit. Members were referred to the recent BMJ article, Crisis in the Supply of Medicines https://www.bmj.com/content/367/bmj.l5841 , which gives a good summary of the current situation. This content is open to BMA members or Open Athens subscribers. The government has taken various steps to try and mitigate the potential impact and serious shortage protocols have recently been used for the first time. **3.Community pharmacy delivery charges** PB raised patient concerns about the recent decision by some community pharmacies to charge for medicines deliveries and the potential impact on vulnerable patients. PC explained that delivery of medication to patients is not covered by the

	community pharmacy NHS terms of service. Pharmacies have provided this service at their own cost to support patients to access their medication when there are difficulties accessing the pharmacy. Over time, this has tended to become a more general service to any patient who has requested delivery. This reduces the opportunity for the pharmacist to interact with patients and ensure patients have the support they need to take their medication correctly. In addition, with previous cuts to the NHS contractual funding and the recent five year agreement to maintain funding at the current level, and inflationary only price increases, it has become unsustainable for pharmacies to provide this service at no cost to patients. Some exemptions apply but these are different from organisation to organisation. The LPC has contacted contractors to express concern at some gaps in the communications strategy around this change and to emphasise that patients should not be directed to GP practices to confirm any eligibility criteria for exemptions to charging.
	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, 14th January 202012:30 pm room 2 Tuesday, 21st April 2020 12:30 pm room 4 Tuesday, 7th July 2020 12:30 pm room 4 Tuesday, 13th October 202012:30 pm room to confirm
	Signed: **Date:** 14/1/20 (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 8th October 2019.**

Classification of products:

R = 'RED' drugs for hospital use only
A = 'AMBER' drugs suitable for use under Shared Care arrangements
G+ = 'GREEN PLUS – Drugs normally recommended or initiated by hospital specialist, but where the provision of an information leaflet may be appropriate to facilitate continuing treatment by GPs. Many of these information sheets are in the process of development.
G = 'GREEN' – Drugs where initiation by GPs is appropriate.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
None				
2) New Requests				
Camellia sinensis extract 10% Ointment (Catephen®)		✓		Camellia sinensis extract 10% Ointment (Catephen®) has been requested as a last line topical treatment for anogenital warts. This is on the grounds that podophyllotoxin solution is difficult to apply and podophyllotoxin cream is currently only available as an unlicensed preparation. Catephen® is twice as effective as placebo for the complete clearance of warts. The committee questioned whether the podophyllotoxin solution was more difficult to apply given it is only applied twice daily for 3 days per week for up to 4 weeks, compared to Catephen® that is applied three times daily for 16 weeks. The high cost and lack of comparative data with other treatments was also noted. **Decision: Refused**
Follitropin delta (Rekovelle®) injection	✓ R			Follitropin delta (Rekovelle®) has been requested for a 100 patient evaluation to establish if the Rekovelle® dosing algorithm is beneficial for women at risk of ovarian hyper stimulation syndrome (OHSS) where standard dosing with FSH results in all or nothing responses. Compared with standard dose rFSH Rekovelle® was non-inferior in terms of ongoing pregnancy rates and had lower rates of excessive ovarian responses and requirements for OHSS interventions. **Decision:** The committee approved the addition of Rekovelle® to the formulary for the purposes of a 100 patient evaluation only. This is subject to the applicants providing a time scale for the evaluation and report of outcomes to the committee.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Patiromer (Veltassa®)		✓		**Patiromer (Veltassa®)** currently has a negative NICE ACD with the final decision expected in February 2020. A recent NTAG decision was that patiromer (Veltassa®) is not recommended for the treatment of hyperkalaemia. **Decision:** The committee will not consider the use of Patiromer (Veltassa®) whilst it is under review by NICE. The NTAG decision stands until that publication.
Del Nido cardioplegia solution	✓ R			Del Nido cardioplegia solution has been requested for use in paediatric and adult congenital cardiac surgery at NUTH. It has been requested on the grounds that it gives prolonged periods of arrest (up to 3 hours) whereas St Thomas's (Harefield) solution has a duration of 25-30 minutes, requiring top up doses. The evidence suggests that the use of Del Nido reduces cross clamp times, bypass times, ventricular fibrillation post cross clamp, and troponin T release post-surgery, with no differences in outcomes at 30 days. Some studies also showed a reduced time on ICU and hospital length of stay. The solution will be prepared in NUTH pharmacy production unit. **Decision:** The committee approved the addition of Del Nido cardioplegia solution to the formulary, subject to the usual governance arrangements for unlicensed medicines being in place.
3) New formulations & extensions to use				
Buprenorphine oral lyophilisate (Espranor®)		✓		Espranor® has been requested by the Chief Pharmacist from Change, Grow, Live, which is an organisation subcontracted by the local health authority to provide substance misuse services in Gateshead. It was recognised that there had been a recent price increase in sublingual buprenorphine. Concerns were raised that this request was potentially being driven by a rebate scheme as the list price is very similar to the other sublingual buprenorphine preparations. There doesn't appear to be consistent support for the use of this product across the APC footprint. Concerns were expressed around patient safety implications including potential variation in bioavailability, confusion arising from multiple dosage forms of buprenorphine and the impact on community pharmacy supervised services. It was felt that the more rapid dissolution may be helpful however no evidence was presented that diversion was reduced. **Decision: Refused**

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Progesterone 25mg SC/IM Injection (Lubion®)	✓ R			Progesterone 25mg SC/IM Injection (Lubion®) has been requested by the Newcastle Fertility Centre for luteal support, in addition to vaginal progesterone, for frozen embryo transfer (FET) cycles in women who've experienced a prior biochemical pregnancy loss in a FET cycle. In fresh embryo cycles Lubion® is non-inferior to progesterone vaginal gel / pessaries. In frozen blastocyst transfer cycles a combination of IM oily progesterone plus progesterone pessaries or IM oily progesterone was more effective than vaginal progesterone alone for luteal support, leading to a significantly higher ongoing pregnancy rate. A different progesterone preparation was used in this study, but the exposure would be similar given the proposed dose of Lubion®. Concerns were raised regarding the generalisability of the results but it was recognised that the Newcastle Fertility Centre continually monitor their outcomes. The applicant has confirmed (post FSC) that women are allowed 3 egg collections cycles on the NHS and that the majority women don't have any eggs left over for subsequent frozen cycles. **Decision:** The committee agreed that Lubion® would be added to the formulary for luteal support in patients who've had a previous failed biochemical pregnancy in a FET cycle. This is subject to a report of outcomes after 40 patients.

4) NHS England Specialised Services communications noted and endorsed by APC	
SSC2034 - NICE TA 569: Pertuzumab for adjuvant treatment of HER2-positive early stage breast cancer	The formulary will reflect the SSC position
SSC2036 - Approval for use for immunoglobulin (Ig) for indications that currently fall into the grey or black categories in Clinical Guidelines for Immunoglobulin use	The formulary will reflect the SSC position
SSC2038 - NICE TA FAD: Cemiplimab for treating metastatic or locally advanced cutaneous squamous cell carcinoma	The formulary will reflect the SSC position
SSC2040 - Nusinersen for treating spinal muscular atrophy Type 1 - Revised Provider Letter	The formulary will reflect the SSC position
SSC2041 - NICE TA FAD: Dacomitinib for untreated EGFR-positive non-small-cell lung cancer	The formulary will reflect the SSC position
SSC2042 - NICE TA: Atezolizumab in combination for treating metastatic non-squamous non-small-cell lung cancer	The formulary will reflect the SSC position
SSC2045 - Withdrawal of Marketing Authorisation for olaratumab (Lartruvo®)	The formulary will reflect the SSC position
SSC2047 - NICE TA FAD: Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer	The formulary will reflect the SSC position
SSC2048 - NICE Highly Specialised Technology HST9: Inotersen for treating hereditary transthyretin amyloidosis	The formulary will reflect the SSC position
SSC2049 - NICE TA 563: Abemaciclib with an aromatase inhibitor for untreated advanced hormone-receptor positive, HER2-negative, locally advanced or metastatic breast cancer	The formulary will reflect the SSC position
SSC2051 - Cholic acid and chenodeoxycholic acid for treating inborn errors of bile acid synthesis	The formulary will reflect the SSC position

Product	Decision: Approved	Refused	Deferred	Comments/notes
SSC2054 - Avelumab in combination with axitinib for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC)				The formulary will reflect the SSC position
SSC2056 - CCP: Sapropterin for Phenylketonuria (all ages)				The formulary will reflect the SSC position
SSC2058 - NICE TA: Brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma. [TA577]				The formulary will reflect the SSC position
SSC2059 - CCP: Treatment for defined patients with multidrug-resistant tuberculosis (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB) including bedaquiline and delamanid				The formulary will reflect the SSC position
SSC2064 - NICE TA FAD: Olaparib tablets for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy				The formulary will reflect the SSC position
SSC2066 - Maternal intravenous immunoglobulin administration for prevention of alloimmune fetal and neonatal haemochromatosis disease: NHS England Reference:1906				The formulary will reflect the SSC position
SSC2069 - NICE TA, Appraisal Consultation Document: Neratinib for extended adjuvant treatment of hormone receptor-positive, HER2-positive early stage breast cancer after adjuvant trastuzumab				The formulary will reflect the SSC position
SSC2070 - NICE TA FAD: Pembrolizumab with carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer				The formulary will reflect the SSC position
SSC2073 - NHS England Commissioning and provision of Hepatitis B Vaccination of patients with Chronic Kidney Disease (CKD)				The formulary will reflect the SSC position
SSC2079 - NICE Highly Specialised Technology HST10: Patisiran for treating hereditary transthyretin amyloidosis				The formulary will reflect the SSC position
SSC2082 - EAMS: Dupilumab in the treatment of adolescent patients ≥12 to <18 years of age with severe atopic dermatitis who have responded inadequately to at least one systemic therapy or where the available systemic therapies				The formulary will reflect the SSC position
5) Products considered by NICE				
TA588 Nusinersen for treating spinal muscular atrophy				The formulary will reflect the NICE position
TA589 Blinatumomab for treating acute lymphoblastic leukaemia in remission with minimal residual disease activity				The formulary will reflect the NICE position
TA590 Fluocinolone acetonide intravitreal implant for treating recurrent non-infectious uveitis				The formulary will reflect the NICE position
TA591 Letermovir for preventing cytomegalovirus disease after a stem cell transplant				The formulary will reflect the NICE position
TA592 Cemiplimab for treating metastatic or locally advanced cutaneous squamous cell carcinoma				The formulary will reflect the NICE position
TA593 Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer				The formulary will reflect the NICE position
TA594 Brentuximab vedotin for untreated advanced Hodgkin lymphoma Terminated appraisal				The formulary will reflect the NICE position
TA595 Dacomitinib for untreated EGFR mutation-positive non-small-cell lung cancer				The formulary will reflect the NICE position

Product	Decision: Approved	Refused	Deferred	Comments/notes
TA596 Risankizumab for treating moderate to severe plaque psoriasis				The formulary will reflect the NICE position
TA597 Dapagliflozin with insulin for treating type 1 diabetes				The formulary will reflect the NICE position
TA598 Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy				The formulary will reflect the NICE position
TA599 Sodium zirconium cyclosilicate for treating hyperkalaemia				The formulary will reflect the NICE position
TA600 Pembrolizumab with carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer				The formulary will reflect the NICE position
TA601 Bezlotoxumab for preventing recurrent Clostridium difficile infection (terminated appraisal)				The formulary will reflect the NICE position
TA602 Pomalidomide with bortezomib and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal)				The formulary will reflect the NICE position
TA603 Lenalidomide with bortezomib and dexamethasone for untreated multiple myeloma (terminated appraisal)				The formulary will reflect the NICE position
HST10 Patisiran for treating hereditary transthyretin amyloidosis				The formulary will reflect the NICE position
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
Andexanet alfa (Ondexxya®), Factor Xa inhibitor antidote.				The formulary will reflect the N – TAG position
Patiromer (as patiromer sorbitex calcium) for the treatment of hyperkalaemia in adults.				The formulary will reflect the N – TAG position
7) Regional Medicines Optimisation Committee (RMOC)				
Recent guidance and publications noted.				
8) Appeals against earlier decisions by the APC				
None				
9) Guidelines. http://www.northoftyneapc.nhs.uk/guidance/				

- Guidance approved
  - Prescribing trans anal irrigation
  - COPD guideline - Approved subject to minor alterations to formatting and title.
  - Cognitive enhancing medications - new guidance to replace existing
    - Acetylcholinesterase leaflet for primary care – Dec 17
    - Memantine information for primary care – Dec 17
  - Blood glucose guideline - update
  - Non-valvular AF in primary care management - update
  - Antipsychotic leaflet - update
  - ADHD SCG Adults - update
  - ADHD SCG Children - update
  - Vitamin D guidance - approved subject to minor grammatical change
- Guidance to retire:
  - Acetylcholinesterase leaflet for primary care – Dec 17
  - Memantine information for primary care – Dec 17

Product	Decision Approved | Refused | Deferred	Comments/notes
10) Miscellaneous decisions by the APC		
IV lidocaine		The committee noted the report detailing adverse events and the number of patients treated with IV lidocaine for post-operative pain from NUTH and NHCFT **Decision**: It was agreed that IV lidocaine could continue to be used for post-operative pain but a further report of adverse events should be submitted to the FSC after 12 months.
Melatonin		Several new licensed preparations of melatonin are now available, including: • Slenyto® 1mg and 5mg tablets – licensed for insomnia in children and adolescents aged 2- 18 with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient. • Melatonin 1mg/ml solution – licensed for the short-term treatment of jet-lag in adults. The committee support the current position of the off label use of Circadian® and the use of unlicensed liquid until a full formal review of all the melatonin products is undertaken in relation to short and long term safety issues, efficacy and costs. This will be progressed through the formulary subcommittee at the December meeting.
Formulary Review		**Chapter 13 – Dermatology products** Further work required: • Discussion with Dermatology required regarding rationalisation of choice of emollients. • Review in relation to the British Association of Dermatology list of unlicensed specials. • Review in line with the NHSE guidance "items not to be routinely prescribed in primary care" and self-care guidance. • Sunscreens. • Oxidisers and dye section. Other items, as indicated in the document submitted to FSC, can be actioned immediately within the formulary. **Chapter 18 – wound management products** The recommendations of a working group of specialist nurses were accepted and will be reflected in the formulary
Olodaterol 2.5mcg /tiotropium 2.5mcg inhaler (Spiolto Respimat®)		Recommend by the inhaler review group as an option for COPD patients who require LABA/LAMA therapy but who are unable to use the dry powder LABA/LAMA inhalers on formulary. **Decision:** approved as above.