NHS

North of Tyne, Gateshead and North Cumbria
Area Prescribing Committee

Minutes of the meeting held on Tuesday 8th January 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
Sue Dickinson	Director of Pharmacy	RDTC
Tim Donaldson	Chief Pharmacist/Controlled Drugs Accountable Officer	NTW
Paul Fieldhouse	Clinical Director of Pharmacy Services	NCUHT
Neil Gammack	Chief Pharmacist	GHFT
Naeem Iqbal	Prescribing Lead	NTCCG
Matthew Lowery	Formulary and Audit Pharmacist	NUTH
Helen Seymour	Senior Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Graham Syers	Prescribing Lead	N CCG
Simon Thomas	Consultant Clinical Pharmacologist	NUTH
Susan Turner	Pharmacist	NECS
Hannah Willoughby	Pharmacist	NGCCG

Apologies

Matt Grove	Consultant Rheumatologist and Head of Service	NHCT
Neil Morris	Medical Director	NG CCG
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

2019/01	**Resignation** The committee noted the resignation of Neil Morris. The chairman wished to note the contribution Neil has made to the committee in recent years both as a CCG representative and as vice chair. Graham Syers, Northumberland CCG GP prescribing lead, was elected as the new vice chair.
2019/02	**Declarations of interest** The committee agreed that annual declarations of interest would no longer be sought as declarations at each meeting would fulfil requirements. No declarations were made for the current meeting.
2019/03	**Appeals against previous decisions** Desmopressin 25 microgram & 50 microgram oral lyophilisate (Noqdirna®) for the treatment of nocturia due to idiopathic nocturnal polyuria in adults. Chris Harding attended to present the appeal. The committee considered: o Original application o Decision notification o Additional information from the urology team at NUTH o An NDA Multi-Disciplinary Review and Evaluation Mr Harding outlined that the Urology department at NUTH is one of the largest in the UK and clinicians have expressed concern that there is geographical inconsistency in access to this product across the country and that nearby units such as Sunderland and Middlesbrough have it on formulary. Whilst recognising this concern the committee noted that the main grounds for appeal were based around some additional analysis of the existing data in the original application rather than any new evidence. Mr Harding emphasised that • Desmopressin 50µg in men increased the time to first void from baseline by approximately 40 minutes compared to placebo (p=0.006) and by approximately two hours compared to baseline. In women, desmopressin 25µg increased the mean time to first nocturnal void by 49 mins compared to placebo (p=0.003) and by approximately 2.5 hours compared to baseline. • Significant increases in health related QoL and sleep quality were observed compared to placebo. • Noqdirna was well tolerated and associated with low risk hyponatraemia and desmopressin does not add to anticholinergic burden which is an important consideration, particularly in the more elderly population. • It was suggested that Noqdirna could also be beneficial in patients with OAB and BPH who have a component of nocturnal polyuria and who remain sub-optimally treated. The committee noted that confidence intervals point to significant placebo effect and that the trial population had not undertaken the full active lifestyle measures before entering the trial. There was concern that there was no strict criteria for defining response to treatment, and when the medication would be stopped, leading to the potential for significant numbers of patients to be initiated and left on medication that is little, if at all, better than placebo. There was also no evidence of superior safety compared with existing options and no evidence was produced that time to first void significantly improves quality of life. The committee rejected the appeal.

2019/04	**Minutes and decision summary from previous meeting.** The following documents were accepted as a true record: • Decision summary from 9/10/18. • Minutes from 9/10/18.
2019/04	**Matters arising not on the agenda or Action Log.** None.
2019/05	**Action Log** The action log was reviewed and will be updated to reflect the following: • 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 in 6 months. Northumbria clinicians have agreed to undertake this audit. Previously an extension to this audit was agreed to Jan 2019. This data is nearly complete and will be presented to the February FSC. • 2017/51 Insulin Degludec (adults). An audit of initiation and continuation/discontinuation criteria, as outlined in the Birmingham Sandwell Amber Drug review form, was required when approval was given. FSC Agenda Item – remove from action log • 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. Northumbria feedback complete but feedback still required from NUTH clinicians. • 2018/27 Atomoxetine 4mg/ml oral solution. The request for atomoxetine 4mg/ml oral solution was approved on the basis that the applicant would provide an audit on use of the liquid for 6 months to ensure strict initiation criteria are adhered to. ADHD clinics, however, are operated from widely dispersed community-based locations and therefore receive only minimal input from NTW Pharmacy.They use FP10 prescriptions when initiating medicines for children and young people therefore, rather than audit, monitoring was done via ePACT2. Assurance is given that use is limited, implying this has remained in the limited cohort of patients who may need this formulation and therefore formulary approval remains. Remove from action log. • 2018/60 MHRA Ulipristal advice impacts on the formulary position.ML to discuss further with Richard Sill (Northumbria) with a view to removal from the formulary. Item outstanding. • 2018/60 Valproate Pregnancy prevention link to be added to the formulary. Action complete – remove from action log • 2018/60 Oxycodone formulary position - oxycodone is being used as a first line agent in fast track surgery in some centres and it was previously agreed that a formulary application was required to support this. FSC Agenda Item – remove from action log. • 2018/61 Catheter formulary task and finish group. Work ongoing.
2019/06	**Report from the Formulary Sub-committee** The formulary website is available at North of Tyne, Gateshead and North Cumbria Area Prescribing Committee Formulary. **Minutes and recommendations from the North of Tyne, Gateshead and North Cumbria FSC meeting held on 26/11/18:** 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:

Bretschneider's HTK Solution (Custodiol®)
Custodiol® has been requested for use in cardioplegia (unlicensed indication) for minimally invasive mitral valve repair surgery in adults. The benefits of this technique include reduced blood loss, decreased pain, faster recovery, better cosmetic results and better patient satisfaction. Harefield solution is currently used in open heart surgery; it has a duration of action of around 20 minutes and is re-administered as required. Custodial® has duration of action of 2 hours and has been requested on the grounds that the administration of cardioplegia solution in minimally invasive mitral valve repair surgery is a more complex process. The evidence suggests similar efficacy to Harefield solution although there was a trend for more patients to experience ventricular arrhythmia with Custodial®. The Formulary Subcommittee were minded to recommend the inclusion of Custodial® onto the formulary as a Red Drug, subject to a satisfactory response from the applicant regarding ventricular arrhythmia, but this has not yet been received.

Bretschneider's HTK Solution (Custodiol®)
Decision: Deferred until satisfactory assurance re ventricular arrhythmia is received. If this is received it was agreed that the chair of the FSC can approve via chairs action.

Hydrocortisone granules (Alkindi®)
Alkindi® has been requested by paediatric endocrinology for replacement therapy for adrenal insufficiency in infants and children (from birth to < 6 years old) who require doses less than 2.5mg. Current practice is to divide or crush 10mg hydrocortisone tablets or use 2.5mg Corlan® pellets (both off label use). The 10mg tablets are crushed and dissolved in water and a proportion given to the child via a syringe. This may lead to imprecise dosing. Alkindi® is significantly more expensive than the existing options.
Following the FSC meeting there has been an MHRA alert outlining that hydrocortisone muco-adhesive buccal tablets are indicated only for local use in the mouth for aphthous ulceration and should not be used for treating adrenal insufficiency. Substitution of licensed oral formulations of hydrocortisone with muco-adhesive buccal tablets can result in insufficient cortisol absorption and, in stress situations, life-threatening adrenal crisis. Prescribers and pharmacists should therefore only consider use of licensed hydrocortisone products for adrenal replacement therapy. In light of this alert approval was granted in ages and doses beyond the original request.

Hydrocortisone granules (Alkindi®)
Decision: Alkindi® was approved for replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to < 18 years old).

	Fentanyl Patches The manufacturers of Mezolar® (a branded generic fentanyl patch) have carried out studies to see how well Mezolar® patches compare with Durogesic® and claim these demonstrated bioequivalence, similar patch adhesion and similar skin tolerability and safety parameters of Mezolar Matrix to Durogesic Dtrans. In addition feedback from local practices suggests that Matrifen doesn't stick as well as Durogesic. The Mezolar® patches are cost equivalent and it was therefore agreed they will replace Matrifen® as the first line formulary choice. Matrifen® will be removed from the formulary but existing patients who are managing well with that product can continue to receive it. **Mezolar® patches** Decision: Mezolar® patches will replace Matrifen® patches on the formulary but Matrifen® can continue to be used in existing patients who are managing well.
2019/07	**Report from the Medicines Guidelines and Use Group** Draft minutes from the meeting held on 26/11 /18 were received and noted. The MGUG prof secretary informed the committee that the terms of reference had been changed slightly to reflect that the decision around RAG rating of medicines, and maintenance of any associated listings, was the responsibility of the FSC. MGUG will work to develop any required shared care guidance once the RAG status has been decided. Guidelines/Information sheets approved: • Gluten Free Guidance – not currently for adoption in North Cumbria. A minor amendment was requested to reflect the rationale for inclusion of a NUTH appendix. Approved subject to this amendment. • 7 day scripts/MDS policy (expiry date extension) • Diabetes guideline (expiry date extension) • Third party ordering (expiry date extension) • Prescribing Intervals (expiry date extension) It was agreed that the Northern England Clinical Networks' Palliative and End of Life Care Guidelines NECN Palliative and End of Life Care Guidelines 2016 would be referenced on the APC website. http://www.northerncanceralliance.nhs.uk/pathway/palliative-and-end-of-life-care/supportive-palliative-and-end-of-life-care-resources/ Two new process tools were presented to the committee for information: • MGUG new guidance scoping document • MGUG expiring guidance flowchart It was noted that North Cumbria representation is needed on MGUG. North Cumbria have existing guidance that will remain in place until due for review, at which point guidance covering the whole APC area will be progressed.
2019/08	**Opioid, Gabapentinoid and Benzodiazepine Use Review Group** GS presented a brief update on work to date to explore the issues behind the national and regional variation in the use of medication for pain. It was acknowledged that this is a multifactorial issue that requires cross-

	organisational engagement to achieve change.
2019/09	**Guidelines standardisation** The NHS needs to reduce variation to ensure best use of resources and maintain performance. The proper use of appropriate guidelines and pathways is key to this. Mark Dornan, clinical chair of Newcastle Gateshead CCG, attended the meeting to: • outline a vision of ensuring that patients receive great care and clinicians have fast easy access to the latest guidelines & local pathways at the click of a button and • to seek APC comment and/or assistance in achieving this. There is significant variation across NENC and a lack of standardisation in the process of creation, distribution, implementation and review of pathways and guidelines. Information which needs to be shared across multiple areas often involves sharing across multiple platforms. These platforms are hard to maintain and are often not kept up to date. As a result, front line staff do not always have easy access to up to date information. Medical Directors at a recent North Integrated Care Partnership (ICP) Joint Clinical Forum have committed to try and progress this work across their area. The APC acknowledged the challenge and agreed to help by providing guidance and advice in the first instance. It was noted that the APC has historically only been involved in the development and approval of guidance which relates to medicines use and the scope of this work is wider than that but the advice available should be transferable. MD intends to pull together a scoping group and will link with DC to ensure there is appropriate representation on that group from APC member organisations.
2019/10	**Consultation and CCG guidance on prescribing in primary care** NHS England continues to partner with NHS Clinical Commissioners (NHSCC) to support clinical commissioning groups (CCGs) in ensuring that they can use their prescribing resources effectively and deliver best patient outcomes from the medicines that their local population uses. A national public consultation has been launched on proposals to update and review commissioning guidance about items that should not be routinely prescribed in primary care. In the majority of cases there are other more effective, safer and/or cheaper alternatives available. CCGs have been asked to engage with their local communities on these proposals where they have not already taken action in this area. The APC noted the consultation, encouraged member organisations to contribute to it, and emphasised that proper implementation of resulting guidance was key.
2019/11	**Cannabis-based products for medicinal use** Following the Government's announcement to reschedule certain cannabis-based products for medicinal use, NHS England has provided guidance which sets out expectations of what this regulatory change will mean in practice. The committee received, and endorsed, the position outlined in the following guidance and set of clinical frequently asked questions (FAQs): • Guidance to clinicians: Cannabis-based products for medicinal use • Additional guidance to clinicians: Cannabis-based products for medicinal use • Cannabis-based products for medicinal use: Frequently Asked Questions • https://www.nhs.uk/conditions/medical-cannabis/ Current advice supports a limited role in: • children and adults with rare, severe forms of epilepsy and

	• adults with vomiting or nausea caused by chemotherapy and only then when other treatments weren't suitable or hadn't helped. There is some evidence medical cannabis can help certain types of pain, though this evidence is not yet strong enough for NHS England to have recommended it for pain relief. The APC noted that the definition of cannabis-based products for medicinal use relates only to cannabis and cannabis preparations (such as extracts from cannabis as well as cannabinoids isolated from cannabis). It does not include synthetic versions of naturally occurring cannabinoids (e.g. Dronabinol) or any non-natural cannabinoids obtained by chemical synthesis (nabilone). The APC has previously approved very limited off-label use of nabilone in the treatment of chronic pain providing that this is undertaken in secondary care by pain consultants, reviewed after one month, and stopped immediately in non-responders. The committee does not endorse the use of any other cannabis-based products for chronic pain.
2019/12	**RMOC** The following RMOC recommendations were received and noted : • RMOC briefing on adalimumab – October 2018 https://www.sps.nhs.uk/articles/rmoc-briefing-on-adalimumab-october-2018/ • RMOC briefing on adalimumab – December 2018 https://www.sps.nhs.uk/articles/rmoc-briefing-on-adalimumab-december/ • RMOC STOMP resources www.sps.nhs.uk/articles/rmoc-stomp-resources/ • RMOC liothyronine guidance http://www.sps.nhs.uk/articles/rmoc-guidance-prescribing-of-liothyronine. The regional medicines optimisation committees have published new guidance on prescribing liothyronine following recent advice on medicines that should not routinely be prescribed in primary care. This new guidance sets out the criteria determining which liothyronine may be prescribed, and provides clear advice on how commissioners, GPs and NHS consultants can work together to ensure use of liothyronine is clinically appropriate and patient treatment is safe and effective. The APC has previously agreed local guidance http://www.northoftyneapc.nhs.uk/wp-content/uploads/sites/6/2018/10/Liothyronine-prescribing-guidance-v0.4.pdf for the review of patients on liothyronine and feel this guidance is still appropriate. • Homely Remedies Guidance www.sps.nhs.uk/articles/rmoc-guidance-homely-remedies/ • RMOC STOMP resources www.sps.nhs.uk/articles/rmoc-stomp-resources/
2019/13	**Northern (NHS) Treatment Advisory Group (N-TAG)** The following recommendations were finalised by NTAG at their meeting on the 20th November 2018 and are now available on the website: • Erenumab and galcanezumab for prophylaxis of migraine – negative appraisal. • Pitolisant (Wakix®) for the treatment of narcolepsy with or without cataplexy in adults (updated) • Actipatch® for management of localised musculoskeletal pain – negative appraisal The formulary will reflect these recommendations.

2019/14	**NICE Technology Appraisals** The formulary will be amended to reflect the following: • TA293 Eltrombopag for treating chronic immune (idiopathic) thrombocytopenic purpura (updated guidance) • TA221 Romiplostim for the treatment of chronic immune (idiopathic) thrombocytopenic purpura • TA542 Cabozantinib for untreated advanced renal cell carcinoma • TA543 Tofacitinib for treating active psoriatic arthritis after inadequate response to DMARDs • TA544 Dabrafenib with trametinib for adjuvant treatment of resected BRAF V600 mutation-positive melanoma • TA545 Gemtuzumab ozogamicin for untreated acute myeloid leukaemia • TA546 Padeliporfin for untreated localised prostate cancer • TA547 Tofacitinib for moderately to severely active ulcerative colitis • TA548 Decitabine for untreated acute myeloid leukaemia (terminated appraisal) • TA549 Denosumab for preventing skeletal-related events in multiple myeloma (terminated appraisal) • TA 550 Vandetanib for treating medullary thyroid cancer • TA551 Lenvatinib for untreated advanced hepatocellular carcinoma – guidance • TA552 Liposomal cytarabine–daunorubicin for untreated acute myeloid leukaemia – guidance • TA553 Pembrolizumab for adjuvant treatment of resected melanoma with high risk of recurrence – guidance • TA554 Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged up to 25 years – guidance
2019/15	**NHS England** The following NHS England communications were noted and will be reflected in the formulary: • SSC1927 - NICE TA FAD: Dabrafenib with trametinib for adjuvant treatment of resected BRAF V600 mutation-positive melanoma • SSC1932 - Outcomes of genomics procurement and commissioning arrangements from the 01 October • SSC1933 - NICE TA FAD: Gemtuzumab ozogamicin for untreated acute myeloid leukaemia • SSC1934 - Clinical Commissioning Policy Statement: Sphenopalatine Ganglion Stimulation in Refractory Chronic Cluster Headache (Adults) • SSC1936 - MHRA Alert: Radium-223 Dichloride: new restrictions on use due to increased risk of fracture and trend for increased mortality seen in a clinical trial • SSC1937 - Commissioning of Palivizumab (To Reduce the Risk of RSV in High Risk Infants) for the 2018 Vaccination Season • SSC1938 - Clinical Commissioning Policy Statement: Rituximab Bio-similar for the Treatment of Myasthenia Gravis [Adults] • SSC1939 - NICE TA 531: Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer • SSC1940 - Highly Specialised Technology Appraisal 8: Burosumab for treating X-linked hypophosphataemia in children and young people • SSC1941 - NICE TA FAD: Liposomal cytarabine–daunorubicin for

	untreated acute myeloid leukaemia • SSC1942 - NICE TA FAD: Lenvatinib for untreated advanced hepatocellular carcinoma • SSC1944 - NICE TA FAD: Dabrafenib with trametinib for adjuvant treatment of resected BRAF V600 mutation-positive melanoma • SSC1945 - NICE TA 535: Lenvatinib and sorafenib for treating differentiated thyroid cancer after radioactive iodine • SSC1946 - NICE TA FAD: Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic, non-squamous non-small-cell lung cancer • SSC1947 - NICE TA FAD: Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged up to 25 years • SSC1948 - NICE TA 538: Dinutuximab beta for treating neuroblastoma • SSC1949 - Clinical Commissioning Policy Statement: Stereotactic Radiosurgery and Stereotactic Radiotherapy for Primary Non-Germ Cell Pineal Tumours (All Ages) • SSC1950 - CCP Statement: Stereotactic Radiosurgery and Stereotactic Radiotherapy for Intracranial Ependymoma (Children) • SSC1951 - NICE TA FAD: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease • SSC1952 - CCP: Clofarabine for relapsed or refractory acute myeloid leukaemia (AML) as a bridge to transplant (all ages) • SSC1953 - NICE TA FAD: Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal B-cell lymphoma after 2 or more systemic therapies • SSC1954 - NICE TA FAD: Regorafenib for treated advanced hepatocellular carcinoma • SSC1955 - NICE TA Final Guidance: Vandetanib for treating medullary thyroid cancer • SSC1956 - NICE TA FAD: Pembrolizumab for adjuvant treatment of resected melanoma with high risk of recurrence
2019/16	**Chair's action** None
2019/17	**Any other business** None
	Date and time of next meeting(s) Tuesday 2nd April 2019 12:30 pm Tuesday 9th July 2019 12:30 pm Tuesday 8th October 2019 12:30 pm
	Signed: **Date:** 2/4/19 (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 January 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				
Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Bretschneider's HTK Solution (Custodiol®)			✓	Custodiol® has been requested for use in cardioplegia (unlicensed indication) for minimally invasive mitral valve repair surgery in adults. Harefield solution is used in open heart surgery; it has a duration of action of around 20 minutes, requiring re-administration. Custodial® has a duration of action of 2 hours and has been requested on the grounds that administration of cardioplegia solution in minimally invasive mitral valve repair surgery is more complex. It has similar efficacy to Harefield solution, except there was a trend towards a higher rate of ventricular arrhythmia with Custodial®. **Decision:** The request for Custodial® was deferred until a satisfactory response from the applicant regarding ventricular arrhythmia was received.Once received, FSC chairs action can be taken to approve.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Hydrocortisone granules (Alkindi®)	✓			Alkindi® has been requested by paediatric endocrinology for replacement therapy for adrenal insufficiency in infants and children (from birth to < 6 years old) who require doses less than 2.5mg. Current practice is to divide or crush 10mg hydrocortisone tablets or use 2.5mg Corlan® pellets (both off label use). The 10mg tablets are crushed and dissolved in water and a proportion given to the child via a syringe. This may lead to imprecise dosing. Following the FSC meeting there has been an MHRA alert outlining that hydrocortisone muco-adhesive buccal tablets are indicated only for local use in the mouth for aphthous ulceration and should not be used for treating adrenal insufficiency. Substitution of licensed oral formulations of hydrocortisone with muco-adhesive buccal tablets can result in insufficient cortisol absorption and, in stress situations, life-threatening adrenal crisis. Prescribers and pharmacists should therefore only consider use of licensed hydrocortisone products for adrenal replacement therapy. In light of this alert approval was granted in ages and doses beyond the original request. **Decision:** The request for Alkindi® was approved for replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to < 18 years old).
Oxycodone - ERAS (Enhanced Recovery After Surgery)	✓			Oxycodone has been requested by the orthopaedic surgeons at NHCFT for short-term management of post-op pain as part of a multi-modal enhanced recovery pathway. The relative benefits of oxycodone vs. morphine remain controversial and oxycodone may be associated with a greater risk of dependency. Concerns were raised regarding patients subsequently requesting oxycodone from their GP. Elective hip and knee surgery patients will be given a maximum of 5 days' supply of oxycodone on discharge which will be stepped down to codeine/paracetamol thereafter. The discharge summary will be very clear and state that the complete course of oxycodone had been given and no further supplies would be given via hospital or GP. **Decision:** The request for oxycodone in ERAS was approved subject to very clear instructions given to patients regarding continuation, and contained within the formulary and discharge summaries.
DEKAs® Plus and DEKAs® Essentials multivitamins	✓			DEKAs Plus (liquid, chewable tablets, softgels) and DEKAs Essentials are multivitamin and mineral supplements for patients with Cystic Fibrosis (CF). DEKAs vitamins contain all the essential fat soluble vitamins (A, D, E and K) in just one tablet which will ease the treatment burden and improve compliance for patients. The use of DEKAs will lead to a small increase in costs. **Decision:** The committee agreed to the inclusion of DEKAs® Plus and DEKAs® Essentials multivitamins on the formulary for adult patients with CF.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
3) New formulations & extensions to use				
None				
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC1927 - NICE TA FAD: Dabrafenib with trametinib for adjuvant treatment of resected BRAF V600 mutation-positive melanoma				The formulary will reflect the Specialised services Circular
SSC1932 - Outcomes of genomics procurement and commissioning arrangements from the 01 October				Noted
SSC1933 - NICE TA FAD: Gemtuzumab ozogamicin for untreated acute myeloid leukaemia				The formulary will reflect the Specialised services Circular
SSC1934 - Clinical Commissioning Policy Statement: Sphenopalatine Ganglion Stimulation in Refractory Chronic Cluster Headache (Adults)				The formulary will reflect the Specialised services Circular
SSC1936 - MHRA Alert: Radium-223 Dichloride: new restrictions on use due to increased risk of fracture and trend for increased mortality seen in a clinical trial				The formulary will reflect the Specialised services Circular
SSC1937 - Commissioning of Palivizumab (To Reduce the Risk of RSV in High Risk Infants) for the 2018 Vaccination Season				The formulary will reflect the Specialised services Circular
SSC1938 - Clinical Commissioning Policy Statement: Rituximab Bio-similar for the Treatment of Myasthenia Gravis [Adults]				The formulary will reflect the Specialised services Circular
SSC1939 - NICE TA 531: Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer				The formulary will reflect the Specialised services Circular
SSC1940 - Highly Specialised Technology Appraisal 8: Burosumab for treating X-linked hypophosphataemia in children and young people				The formulary will reflect the Specialised services Circular
SSC1941 - NICE TA FAD: Liposomal cytarabine–daunorubicin for untreated acute myeloid leukaemia				The formulary will reflect the Specialised services Circular
SSC1942 - NICE TA FAD: Lenvatinib for untreated advanced hepatocellular carcinoma				The formulary will reflect the Specialised services Circular
SSC1944 - NICE TA FAD: Dabrafenib with trametinib for adjuvant treatment of resected BRAF V600 mutation-positive melanoma				The formulary will reflect the Specialised services Circular
SSC1945 - NICE TA 535: Lenvatinib and sorafenib for treating differentiated thyroid cancer after radioactive iodine				The formulary will reflect the Specialised services Circular
SSC1946 - NICE TA FAD: Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic, non-squamous non-small-cell lung cancer				The formulary will reflect the Specialised services Circular
SSC1947 - NICE TA FAD: Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged up to 25 years				The formulary will reflect the Specialised services Circular
SSC1948 - NICE TA 538: Dinutuximab beta for treating neuroblastoma				The formulary will reflect the Specialised services Circular
SSC1949 - Clinical Commissioning Policy Statement: Stereotactic Radiosurgery and Stereotactic Radiotherapy for Primary Non-Germ Cell Pineal Tumours (All Ages)				The formulary will reflect the Specialised services Circular
SSC1950 - CCP Statement: Stereotactic Radiosurgery and Stereotactic Radiotherapy for Intracranial Ependymoma (Children)				The formulary will reflect the Specialised services Circular

SSC1951 - NICE TA FAD: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease	The formulary will reflect the Specialised services Circular
SSC1952 - CCP: Clofarabine for relapsed or refractory acute myeloid leukaemia (AML) as a bridge to transplant (all ages)	The formulary will reflect the Specialised services Circular
SSC1953 - NICE TA FAD: Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal B-cell lymphoma after 2 or more systemic therapies	The formulary will reflect the Specialised services Circular
SSC1954 - NICE TA FAD: Regorafenib for treated advanced hepatocellular carcinoma	The formulary will reflect the Specialised services Circular
SSC1955 - NICE TA Final Guidance: Vandetanib for treating medullary thyroid cancer	The formulary will reflect the Specialised services Circular
SSC1956 - NICE TA FAD: Pembrolizumab for adjuvant treatment of resected melanoma with high risk of recurrence	The formulary will reflect the Specialised services Circular
5) Products considered by NICE	
TA293 Eltrombopag for treating chronic immune (idiopathic) thrombocytopenic purpura (updated guidance)	The formulary will reflect the NICE Guidance
TA221 Romiplostim for the treatment of chronic immune (idiopathic) thrombocytopenic purpura	The formulary will reflect the NICE Guidance
TA542 Cabozantinib for untreated advanced renal cell carcinoma	The formulary will reflect the NICE Guidance
TA543 Tofacitinib for treating active psoriatic arthritis after inadequate response to DMARDs	The formulary will reflect the NICE Guidance
TA544 Dabrafenib with trametinib for adjuvant treatment of resected BRAF V600 mutation-positive melanoma	The formulary will reflect the NICE Guidance
TA545 Gemtuzumab ozogamicin for untreated acute myeloid leukaemia	The formulary will reflect the NICE Guidance
TA546 Padeliporfin for untreated localised prostate cancer	The formulary will reflect the NICE Guidance
TA547 Tofacitinib for moderately to severely active ulcerative colitis	The formulary will reflect the NICE Guidance
TA548 Decitabine for untreated acute myeloid leukaemia (terminated appraisal)	The formulary will reflect the NICE Guidance
TA549 Denosumab for preventing skeletal-related events in multiple myeloma (terminated appraisal)	The formulary will reflect the NICE Guidance
TA 550 Vandetanib for treating medullary thyroid cancer	The formulary will reflect the NICE Guidance
TA551 Lenvatinib for untreated advanced hepatocellular carcinoma – guidance	The formulary will reflect the NICE Guidance
TA552 Liposomal cytarabine–daunorubicin for untreated acute myeloid leukaemia – guidance	The formulary will reflect the NICE Guidance
TA553 Pembrolizumab for adjuvant treatment of resected melanoma with high risk of recurrence – guidance	The formulary will reflect the NICE Guidance
TA554 Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged up to 25 years – guidance	The formulary will reflect the NICE Guidance

6) Northern (NHS) Treatment Advisory Group (N-TAG)

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Erenumab and galcanezumab for prophylaxis of migraine		✓		The formulary will reflect the N-TAG recommendation http://ntag.nhs.uk/docs/rec/NTAG%20Decision%20Summary%20Erenumab%20and%20galcanezumab%20for%20prophylaxis%20of%20migraine.pdf
Pitolisant (Wakix®) for the treatment of narcolepsy with or without cataplexy in adults (updated)				The formulary will reflect the N-TAG recommendation http://ntag.nhs.uk/docs/rec/NTAG%20Decision%20Summary%20Pitolisant%20-%20updated%20November%202018%20-%20%20FINAL.pdf
Actipatch® for management of localised musculoskeletal pain		✓		The formulary will reflect the N-TAG recommendation http://ntag.nhs.uk/docs/rec/NTAG%20Decision%20Summary%20Actipatch%20for%20management%20of%20localised%20musculoskeletal%20pain.pdf

7) Appeals against earlier decisions by the APC

Desmopressin 25 microgram & 50 microgram oral lyophilisate (Noqdirna®) for the treatment of nocturia due to idiopathic nocturnal polyuria in adults.		✓		The committee noted that confidence intervals point to significant placebo effect and that the trial population had not undertaken the full active lifestyle measures before entering the trial. There was concern that there was no strict criteria for defining response to treatment, and when the medication would be stopped, leading to the potential for significant numbers of patients to be initiated and left on medication that is little, if at all, better than placebo. There was also no evidence of superior safety compared with existing options and no evidence was produced that time to first void significantly improves quality of life. The committee rejected the appeal.

8) Guidelines approved.

Gluten Free	Guidance approved for North of Tyne and Gateshead areas. Not currently for adoption in North Cumbria.
7 day scripts/MDS policy (expiry date extension)	
Diabetes guideline (expiry date extension)	
Third party ordering (expiry date extension)	
Prescribing Intervals (expiry date extension)	

NECN Palliative and End of Life Care Guidelines 2016	It was agreed that the Northern England Clinical Networks' Palliative and End of Life Care Guidelines NECN Palliative and End of Life Care Guidelines 2016 would be referenced on the APC website. http://www.northerncanceralliance.nhs.uk/pathway/palliative-and-end-of-life-care/supportive-palliative-and-end-of-life-care-resources/
9) Miscellaneous decisions by the APC	
Fentanyl Patches	The manufacturers of Mezolar® (a branded generic fentanyl patch) have carried out studies to see how well Mezolar® patches compare with Durogesic® and claim these demonstrated bioequivalence, similar patch adhesion and similar skin tolerability and safety parameters of Mezolar Matrix to Durogesic Dtrans. In addition feedback from local practices suggests that Matrifen doesn't stick as well as Durogesic. The Mezolar® patches are cost equivalent and it was therefore agreed they will replace Matrifen® as the first line formulary choice. Matrifen® will be removed from the formulary but existing patients who are managing well with that product can continue to receive it. **Decision:** Mezolar® patches will replace Matrifen® patches on the formulary but Matrifen® can continue to be used in existing patients who are managing well.
Cannabis-based products for medicinal use	Following the Government's announcement to reschedule certain cannabis-based products for medicinal use, NHS England has provided guidance which sets out expectations of what this regulatory change will mean in practice. The committee received, and endorsed, the position outlined in the following guidance and set of clinical frequently asked questions (FAQs): • Guidance to clinicians: Cannabis-based products for medicinal use • Additional guidance to clinicians: Cannabis-based products for medicinal use • Cannabis-based products for medicinal use: Frequently Asked Questions • https://www.nhs.uk/conditions/medical-cannabis/ Current advice supports a limited role in: • children and adults with rare, severe forms of epilepsy and • adults with vomiting or nausea caused by chemotherapy and only then when other treatments weren't suitable or hadn't helped. There is some evidence medical cannabis can help certain types of pain, though this evidence is not yet strong enough for NHS England to have recommended it for pain relief. The APC noted that the definition of cannabis-based products for medicinal use relates only to cannabis and cannabis preparations (such as extracts from cannabis as well as cannabinoids isolated from cannabis). It does not include synthetic versions of naturally occurring cannabinoids (e.g. Dronabinol) or any non-natural cannabinoids obtained by chemical synthesis (nabilone). The APC has previously approved very limited off-label use of nabilone in the treatment of chronic pain providing that this is undertaken in secondary care by pain consultants, reviewed after one month, and stopped immediately in non-responders. The committee does not endorse the use of any other cannabis-based products for chronic pain.
Formulary Review	It was agreed to remove co-codamol from the formulary.