NHS

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®)	✓ G+			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)	✓ R			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	✓ G+			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.