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 6th July 2021.**

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				
Cefiderocol	✓ R			Cefiderocol has been requested for the treatment of infections with gram negative aerobic bacteria in patients with limited treatment options. It has a novel mechanism of uptake into bacterial cells and is resistant to all classes of beta lactamases. Decision: Approved as a RED drug in line with the above criteria. To be used on the advice of microbiology and ID physicians only.
Delafloxacin	✓ R			Delafloxacin is an anionic fluoroquinolone with broad spectrum activity. It has been requested for acute bacterial skin and skin structure infections (ABSSSI) where other antibiotics are inappropriate, either due to resistant organisms or intolerance/allergy. Decision: Approved as a RED drug in line with the above criteria. To be used on the advice of microbiology and ID physicians only.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Nexobrid®	✓ R			Nexobrid® is an enzyme-based debriding agent that consists of a partially purified mixture of proteolytic enzymes enriched in bromelain. It has been requested for the removal of eschar in adults with deep partial and full thickness thermal burns. Compared to standard of care for partial and full thickness burns Nexobrid® treated burns required less percentage of the wound area to be excised, less autographs, and less percentage of the wound area autografted. Decision: Approved as a RED drug
3) New formulations & extensions to use				
Anakinra for islet cell transplantation	✓ R			Anakinra has been requested as part of a protocol including alemtuzumab and etanercept for islet cell transplantation to improve outcomes e.g. insulin independence. Decision: Extended indication approved as part of the protocol with alemtuzumab and etanercept for islet cell transplantation
Rivaroxaban granules	✓ G			Requested by the paediatric haematologists at NUTH for the treatment of VTE in children. Decision: Approved for this and in patients with swallowing difficulties.
Hydrocortisone Sodium Phosphate Preservative Free Eye Drops (Softacort®)			✓	Requested for the treatment of mild non-infectious allergic or inflammatory conjunctival diseases. It was noted that there are no published head-to-head studies comparing Softacort® with other low potency (or any other) topical ocular corticosteroids. Weak evidence suggests that Softacort® isn't associated with an increase in ocular pressure. The group felt that it wasn't clear which patients this would be used in and when this would be used in relation to the other ocular steroid preparations. The group also recognised that there was a need for an overall review of the dry formulary / pathway. Decision: Deferred

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	Approved	Refused	Deferred	
Nasal Naloxone (Nyxoid®)	✓ R			A naloxone nasal spray may offer a simpler and more convenient method of administration by non-healthcare professionals. In addition, it avoids the risk of needlestick injuries associated with intramuscular injection. As with all naloxone products the key message is one of ensuring emergency services are called whilst using rescue medication to 'buy time' before they arrive. Decision: Approved as a suitable alternative, for purpose of limited therapeutic pilot, under following circumstances: - Plummer court staff use (Specialist addictions service – Day unit patients) to gain a better understanding of use in practice - Carers (of addicitons service users – Plummer Court) who are unwilling to use Prenoxad - Addictions service users (Plummer Court) who would normally require carers to administer naloxone - Addictions service users (Plummer Court) who continuously fail to carry Prenoxad due to stigma etc - Partners (ie police, who would not normally use the injectable formulation, where nyxoid is more acceptable to use) - Supply by the following CNTW Community Drug and Alcohol Services in accordance with local written process/protocols for Nyxoid distribution: o Newcastle Treatment and Recovery (NTaR) o Northumberland Recovery Partnership (NRP) o North Tyneside Recovery Partnership (NTRP) The results of a planned 12-month review should be brought back to the formulary subcommittee.

Product	Decision Approved | Refused | Deferred	Comments/notes
4) NHS England Specialised Services communications noted and endorsed by APC		
SSC2247 NICE Technology Appraisal Final Appraisal Determination: Trastuzumab deruxtecan for treating HER2- positive unresectable or metastatic breast cancer after 2 or more anti-HER2 therapies		The formulary will reflect the SSC position
SSC2248 NICE Technology Appraisal Final Appraisal Determination: atezolizumab monotherapy for untreated advanced non-small-cell lung cancer		The formulary will reflect the SSC position
SSC2251 - Nivolumab for prev treated unresectable adv oesophageal cancer		The formulary will reflect the SSC position
SSC2252 - osimertinib adjuvant EGFR +ve NSCLC		The formulary will reflect the SSC position
SSC2253 - Pembro 1L MSI-H MMR colorectal cancer		The formulary will reflect the SSC position
SSC2262 NICE Technology Appraisal Final Appraisal Determination: enzalutamide for treating hormone-sensitive metastatic prostate cancer		The formulary will reflect the SSC position
SSC2263 NICE Technology Appraisal Final Appraisal Determination: nivolumab with ipilimumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency		The formulary will reflect the SSC position
5) Products considered by NICE		
TA692 Pembrolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy Negative appraisal		The formulary will reflect the NICE position
TA693 Olaparib plus bevacizumab for maintenance treatment of advanced ovarian, fallopian tube or primary peritoneal cancer		The formulary will reflect the NICE position
TA694 Bempedoic acid with ezetimibe for treating primary hypercholesterolaemia or mixed dyslipidaemia		The formulary will reflect the NICE position. RAG status of Bempedoic acid should be green but there will be a formulary annotation highlighting that use should only be in line with the TAG and that the statin intolerance pathway outlined in the NEELI guidance should be followed before escalating treatment in line with the TAG.
TA695 Carfilzomib with dexamethasone and lenalidomide for previously treated multiple myeloma		The formulary will reflect the NICE position
TA696 Tafamidis for treating transthyretin amyloidosis with cardiomyopathy – negative appraisal		The formulary will reflect the NICE position

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TA697 Andexanet alfa for reversing anticoagulation from apixaban or rivaroxaban		The formulary will reflect the NICE position
TA698 Ravulizumab for treating paroxysmal nocturnal haemoglobinuria		The formulary will reflect the NICE position
TA699 Ofatumumab for treating relapsing multiple sclerosis		The formulary will reflect the NICE position
TA700 Selinexor with low-dose dexamethasone for treating refractory multiple myeloma (terminated appraisal)		The formulary will reflect the NICE position
TA701 Crisaborole for treating mild to moderate atopic dermatitis in people 2 years and older (terminated appraisal)		The formulary will reflect the NICE position
TA702 Ibrutinib with obinutuzumab for untreated chronic lymphocytic leukaemia and small lymphocytic lymphoma (terminated appraisal)		The formulary will reflect the NICE position
TA703 Ibrutinib with rituximab for untreated chronic lymphocytic leukaemia (terminated appraisal)		The formulary will reflect the NICE position
TA704 Trastuzumab deruxtecan for treating HER2-positive unresectable or metastatic breast cancer after 2 or more anti-HER2 therapies		The formulary will reflect the NICE position
TA705 Atezolizumab monotherapy for untreated advanced non-small-cell lung cancer		The formulary will reflect the NICE position
TA706 Ozanimod for treating relapsing–remitting multiple sclerosis – negative appraisal		The formulary will reflect the NICE position
TA707 Nivolumab for previously treated unresectable advanced or recurrent oesophageal cancer		The formulary will reflect the NICE position
TA708 Budesonide orodispersible tablet for inducing remission of eosinophilic oesophagitis		The formulary will reflect the NICE position
TA709 Pembrolizumab for untreated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency		The formulary will reflect the NICE position
TA710 Ravulizumab for treating atypical haemolytic uraemic syndrome		The formulary will reflect the NICE position
TA711 Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs		The formulary will reflect the NICE position
6) Northern (NHS) Treatment Advisory Group (N-TAG)		
Perampanel (Fycompa®) for Partial-onset (focal) epilepsy – updated recommendation to include license extension in children under 12 years old.		The formulary will reflect the N – TAG position

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Transanal Irrigation Systems (TAIs) for neurogenic bowel dysfunction, chronic constipation, and chronic faecal incontinence – updated to replace Peristeen with Peristeen Plus as Peristeen discontinued by manufacturer.		The formulary will reflect the N – TAG position
Infliximab Subcutaneous (Remsima®) – reviewed and no change to recommendation that this is an option during Covid-19 Pandemic. To be reviewed again in 6 months.		The formulary will reflect the N – TAG position
Dupilumab and Omalizumab for chronic rhinosinusitis with nasal polyps - updated to note that not recommended as NICE TA terminated.		The formulary will reflect the NICE position
Transcutaneous vagus nerve stimulation for treatment of cluster headache and migraine – updated to reflect change in funding arrangements. Now CCG commissioned and funded.		The formulary will reflect the N – TAG position
7) Regional Medicines Optimisation Committee (RMOC)		
Shared care consultations noted.		
8) Appeals against earlier decisions by the APC		
None		
9) Guidelines approved. http://www.northoftyneapc.nhs.uk/guidance/		
Antiplatelet guidance		Updated guidance
Prescribing intervals		Updated guidance
Children`s ADHD shared care guidance		Updated guidance
Melatonin shared care guidance for the management of Sleep/Wake Disorders in Children and Young People: update.		The main changes to the guidance are that each shared care agreement is time limited to 2 years at which point a formal review is to be undertaken by secondary care and a new shared care agreement requested if needed. There should also be at least an annual trial off treatment.
Bariatric surgery - management of patients, post-bariatric surgery, in primary care - update		Updated guidance
Immunosuppression following liver transplant		Updated guidance
10) Miscellaneous decisions by the APC		
None		