



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 12th January 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				
Methylphenidate for long-term use in post-cancer treatment			✓	<p>Methylphenidate immediate release tablets have been requested for survivors of childhood acute lymphoblastic leukaemia and brain tumours to improve cognitive function. Shared care would be required with secondary care initiating the treatment and carrying out annual reviews and primary care taking over the prescribing responsibility after three months. The committee was minded to approve the extended role although some concerns were expressed around prescribing off label, for what is effectively a trial situation, and about how the transition from paediatric into adult care would be handled.</p> <p>Decision: Prior to approval a specific shared care agreement will be required to clarify this is a niche indication and to outline the responsibilities of all involved.</p>
3) New formulations & extensions to use				
Atorvastatin 30mg and 60mg		✓		<p>Atorvastatin 30mg and 60mg strengths are being introduced to the market at a much higher cost than the original strengths. The formulary will have the currently approved strengths added so that these higher cost variations are not included.</p>
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC2184 - NICE Technology Appraisal Final Appraisal Determination: darolutamide with androgen deprivation therapy for treating hormone-relapsed non-metastatic prostate cancer			The formulary will reflect the SSC position	

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SSC2190 - Early Access to Medicines Scheme – Berotralstat for routine prevention of recurrent attacks of hereditary angioedema (HAE) in adult and adolescent patients aged 12 years and older				The formulary will reflect the SSC position
SSC2191 - Entrectinib, larotrectinib and genomic testing for neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumours.				The formulary will reflect the SSC position
SSC2192 - Pharmacogenomic testing for DPYD polymorphisms with fluoropyrimidine therapies.				The formulary will reflect the SSC position
SSC2195 - NICE Technology Appraisal Final Appraisal Determination - Atezolizumab with bevacizumab for treating advanced or unresectable hepatocellular carcinoma.				The formulary will reflect the SSC position
SSC2198 Policy revision: plerixafor for stem cell mobilisation in adults and children				The formulary will reflect the SSC position
SSC2199 Encorafenib plus cetuximab for previously treated BRAF V600E mutation-positive metastatic colorectal cancer				The formulary will reflect the SSC position
SSC2200 Clinical Commissioning Policy (Revised): Use of defibrotide in severe veno-occlusive disease following stem cell transplant.				The formulary will reflect the SSC position
SSC2202 Clinical Commissioning Policy: Mercaptamine hydrochloride viscous eyedrops for corneal cystine deposits in people aged older than 2 years – not for routine commissioning.				The formulary will reflect the SSC position
SSC2203 is regarding NHS England Clinical Commissioning Policy: Sapropterin for Phenylketonuria (all ages).				The formulary will reflect the SSC position
SSC2206 - acalabrutinib for treating chronic lymphocytic leukaemia				The formulary will reflect the SSC position
SSC2207 - brigatinib for ALK-positive advanced non-small-cell lung cancer				The formulary will reflect the SSC position
SSC2208 - NHS England Funding Position for NICE TA439 - Cetuximab and panitumumab for previously untreated metastatic colorectal cancer				The formulary will reflect the SSC position
SSC2209 - Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis				The formulary will reflect the SSC position
5) Products considered by NICE				
Early access to medicines scheme (EAMS) scientific opinion: Berotralstat in the treatment of hereditary angioedema				The formulary will reflect the NICE position
HST13 Volanesorsen for treating familial chylomicronaemia syndrome				The formulary will reflect the NICE position
TA653 Osimertinib for treating EGFR T790M mutation-positive advanced non-small-cell lung cancer				The formulary will reflect the NICE position
TA654 Osimertinib for untreated EGFR mutation-positive non-small-cell lung cancer				The formulary will reflect the NICE position
TA655 Nivolumab for advanced squamous non-small-cell lung cancer after chemotherapy				The formulary will reflect the NICE position
TA656 Siponimod for treating secondary progressive multiple sclerosis				The formulary will reflect the NICE position
TA657 Carfilzomib for previously treated multiple myeloma				The formulary will reflect the NICE position

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TA658 Isatuximab with pomalidomide and dexamethasone for treating relapsed and refractory multiple myeloma				The formulary will reflect the NICE position
TA659 Galcanezumab for preventing migraine				The formulary will reflect the NICE position
TA660 Darolutamide with androgen deprivation therapy for treating hormone-relapsed non-metastatic prostate cancer				The formulary will reflect the NICE position
TA661 Pembrolizumab for untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma				The formulary will reflect the NICE position
TA663 Venetoclax with obinutuzumab for untreated chronic lymphocytic leukaemia				The formulary will reflect the NICE position
TA664 Liraglutide for managing overweight and obesity				The formulary will reflect the NICE position
TA665 Upadacitinib for treating severe rheumatoid arthritis				The formulary will reflect the NICE position
TA666 Atezolizumab with bevacizumab for treating advanced or unresectable hepatocellular carcinoma				The formulary will reflect the NICE position
TA667 Cuplacizumab with plasma exchange and immunosuppression for treating acute acquired thrombotic thrombocytopenic purpura				The formulary will reflect the NICE position
TA668 Encorafenib plus cetuximab for previously treated BRAF V600E mutation-positive metastatic colorectal cancer				The formulary will reflect the NICE position
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
Infliximab Subcutaneous (Remsima®) The previous recommendation has been updated to include reference to license extension for Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and psoriasis plus making reference to recently published NICE evidence summary on infliximab SC in rheumatoid arthritis				The formulary will reflect the N – TAG position
Solriamfetol for obstructive sleep apnoea in adults				The formulary will reflect the N – TAG position
Solriamfetol for narcolepsy in adults				The formulary will reflect the N – TAG position
Teriparatide Biosimilar				The formulary will reflect the N – TAG position
Dupilumab and Omalizumab for chronic rhinosinusitis with nasal polyps				The formulary will reflect the N – TAG position
Flash Glucose Monitoring updated to include Learning Disability on insulin as an additional criterion as per latest NHSE criteria for reimbursement				The formulary will reflect the N – TAG position
Liraglutide (Saxenda®) for Obesity in adults				Guidance retired. The formulary will reflect the NICE position
7) Regional Medicines Optimisation Committee (RMOC)				
No new publications to note				

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8) Appeals against earlier decisions by the APC				
Ostenil Plus	As this appeal hearing had already been re-scheduled more than once the committee agreed that they would be unable to extend the date to hear this appeal further and that a new formulary submission would need to be made before further consideration was given to approval. Application was therefore formally rejected.			
9) Guidelines approved. http://www.northoftyneapc.nhs.uk/guidance/				
Cow`s Milk and Protein allergy guidance				Update to existing guidance
Oral nutritional supplements formulary and guidance				New
10) Miscellaneous decisions by the APC				
Rosuvastatin – formulary status				The Northern England Evaluation and Lipid Intensification steering group (NEELI) are updating guidance for the use of cholesterol lowering drugs in Northern England. As well as including rosuvastatin as an option in its statin intensity table, the NEELI guidance advises that it may be used as an alternative to atorvastatin for primary or secondary prevention if compatible with other drug therapy. A request to change the status of rosuvastatin from GREEN+ to GREEN was therefore approved.
Oral Vitamin B Supplementation				Recent RMOC guidance around oral vitamin B supplementation has been published leading to a request for a formulary status change to enable Vitamin B Compound Strong to be prescribed across both primary and secondary care for the niche situations described in the RMOC guidance https://www.sps.nhs.uk/wp-content/uploads/2019/12/RMOC-position-statement-oral-vitamin-B-supplementation-in-alcoholism-v1.0-1.pdf . The committee approved the status change of oral vitamin B supplementation from RED to GREEN+ only for the situations described in the RMOC guidance.