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 13th October 2020.**

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				
Betamethasone valerate 0.1% Medicated Plaster (Betesil®)	✓ G+			At the July meeting the committee agreed that Betamethasone valerate 0.1% Medicated Plaster (Betesil®) could be added to the formulary, subject to the production of a clear algorithm for use being approved by the FSC, and dependent on the removal of Fludroxycortide (Haelan®) tape. This algorithm has now been produced. **Decision:** Betesil® will be added to the formulary as a Green plus product; it was further agreed to remove Haelan® tape from the formulary.
2) New Requests				
Meropenem / vaborbactam (Vaborem®)	✓ R			Vaborem® is a combination of meropenem and vaboractam. Vaboractam is a new class of betalactamase inhibitor that extends the activity of meropenem against some carbapenemase producing organisms. It has been requested for use in patients who have limited treatment options where they have suspected or confirmed infections with carbapenemase producing organisms (alone or in combination). **Decision:** Meropenem / vaborbactam (Vaborem®)will be added to the formulary, as a Red drug, for use on microbiology / ID advice.

3) New formulations & extensions to use				
Testosterone sachets (Testogel®)	✓ G+			Off license Testosterone sachets (Testogel®) have been requested as an option to increase libido in menopausal women. Testosterone is recommended in NICE guidance for women with low sexual desire if HRT alone is not effective. **Decision:** The committee approved Testogel® for the treatment of low sexual desire, as a second line option after HRT, in line with NICE guidance (as a Green Plus Drug). Patients will be transferred to GP prescribing after efficacy confirmed / or after patient is stabilised following dose increase in the event of lack of response (undertaken by specialist team).
Dexamfetamine 10mg and 20mg tablets	✓ A			Dexamfetamine 5mg tablets are currently listed on the formulary; 10 mg and 20mg strengths are also available and at a similar cost (pro rata) and will therefore be added to the formulary to allow flexibility in dosing.
Teriparatide Biosimilar	✓ R			The formulary listing for teriparatide is generic but there are now two different brands of teriparatide biosimilar available (Movymia and Terrosa). Both products will be added by brand name to the formulary to ensure consistency of device.
Sildenafil tablets - secondary Raynaud's	✓ G+			Sildenafil, when used for secondary Reynaud's will have a green plus status rather than red to avoid patients routinely having to attend hospital to collect medication when a clinical review is not required. The formulary, and referral letters, will be annotated to make it clear that this is an off label indication.

4) NHS England Specialised Services communications noted and endorsed by APC	
SSC2171 - NICE Technology Appraisal Final Appraisal Determination - polatuzumab vedotin with rituximab and bendamustine for treating relapsed or refractory diffuse large B-cell lymphoma	The formulary will reflect the SSC position
SSC2175 - Avelumab as monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma whose disease has not progressed following first-line platinum-based induction chemotherapy	The formulary will reflect the SSC position
SSC2176 - NICE Technology Appraisal Final Appraisal Determination: osimertinib for untreated EGFR mutation-positive non-small-cell lung cancer (rapid review of TA621)	The formulary will reflect the SSC position
SSC2177 - Hereditary Angioedema (HAE) Supply disruption – Danazol – 100mg-200mg capsules	Noted
SSC2178 - nivolumab adv non-squamous NSCLC after chemotherapy	The formulary will reflect the SSC position

5) Products considered by NICE	
(EAMS) : Dupilumab in the treatment of children aged 6 to 11 years of age with severe atopic dermatitis (allergic eczema)	The formulary will reflect the NICE position
(EAMS) : Nivolumab for treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal cancer after prior chemotherapy	The formulary will reflect the NICE position
Early access to medicines scheme (EAMS) scientific opinion: Avelumab in the treatment of bladder cancer	The formulary will reflect the NICE position

TA640 Treosulfan with fludarabine for malignant disease before allogeneic stem cell transplant	The formulary will reflect the NICE position
TA641 Brentuximab vedotin in combination for untreated systemic anaplastic large cell lymphoma	The formulary will reflect the NICE position
TA642 Gilteritinib for treating relapsed or refractory acute myeloid leukaemia	The formulary will reflect the NICE position
TA643 Entrectinib for treating ROS1-positive advanced non-small-cell lung cancer	The formulary will reflect the NICE position
TA644 Entrectinib for treating NTRK fusion-positive solid tumours	The formulary will reflect the NICE position
TA645 Avelumab with axitinib for untreated advanced renal cell carcinoma	The formulary will reflect the NICE position
TA649 Polatuzumab vedotin with rituximab and bendamustine for treating relapsed or refractory diffuse large B-cell lymphoma	The formulary will reflect the NICE position
TA650 Pembrolizumab with axitinib for untreated advanced renal cell carcinoma – negative appraisal	The formulary will reflect the NICE position
TA651Naldemedine for treating opioid-induced constipation	The formulary will reflect the NICE position

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

Infliximab Subcutaneous (Remsima®) guidance - updated	The formulary will reflect the N – TAG position
Transanal Irrigation Systems (TAIs) for neurogenic bowel dysfunction, chronic constipation, and chronic faecal incontinence - updated	The formulary will reflect the N – TAG position
Airsonett® laminar flow device for treatment of uncontrolled allergic asthma	The formulary will reflect the N – TAG position
Brolucizumab for wAMD	The formulary will reflect the N – TAG position
Semaglutide (oral) for type 2 diabetes	The formulary will reflect the N – TAG position
Gastro-intestinal stimulation with the Enterra™ device for Gastroparesis (NETAG) – retired	Guidance superseded by national guidance

7) Regional Medicines Optimisation Committee (RMOC)

Verbal update given – RMOCs were suspended during COVID-19 but the work plan has started again.

8) Appeals against earlier decisions by the APC

None

9) Guidelines approved/retired. http://www.northoftyneapc.nhs.uk/guidance/

Guidelines approved:

- Northern England Evaluation and Lipid Intensification guideline (NEELI)
- Guidelines for the Management of Adults with Asymptomatic Liver Function Abnormalities
- Amiodarone shared care guidance
- Apomorphine shared care guidance
- Agomelatine - Prescribing and Monitoring in Adults: Information for Primary Care
- Stoma - Prescribing Guidelines for Stoma Accessories (Adult)
- Shared Care Guidelines for Immunosuppressive Treatment for Paediatric Nephrotic Syndrome
- Sativex (delta-9-tetrahydrocannabinol / cannabidiol) Oromucosal Spray Shared Care Guidance

Guidance to retire:

- Hypertension guidelines

10) Miscellaneous decisions by the APC	
OAB drug choices	The local OAB treatment guidelines have been reviewed and updated in line with new NICE guidance. This has prompted a review of the current formulary positioning of medications used. The formulary will be updated to include oxybutynin, solifenacin and tolterodine, listed in that order with no first line choice specified. Darifenacin and propantheline will be removed. A statement will be added to the local OAB guidance regarding onward referral after failure of 2 antimuscarinics and / or mirabegron.
Acetylcysteine 5% drops	Acetylcysteine 5% eye drops are now licensed. The formulary will reflect this change in status.