North of Tyne, Gateshead and North Cumbria Area Prescribing Committee

Summary of decisions made at APC meetings in April and July 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				
None				
2) New Requests				
Sucralfate suspension	✓ Mixed green and red status			Sucralfate suspension was removed from the formulary in July 2017 following a chapter review on the grounds that it was a low use product and, at the time, no licensed product available. It has subsequently been requested for: • Short term use post Radio Frequency Ablation (RFA) for Barret's Oesophagus & Endoscopic Mucosal Resection (EMR). • Bile Reflux (usually post oesophagectomy) in patients in patients who have failed PPI treatment. Approx. 20 – 60 patients per year. Northumbria confirmed that they also use it for stomal ulceration and biliary gastritis in approx. 10-15 patients per year. A literature search didn't identify any studies that specifically looked at the use of sucralfate in patients with bile reflux following oesophagectomy but it has been compared to PPI in other patient groups. A licensed product is now available from Alliance Healthcare. **Decision:** Approved with a 'Red' status for post RFA and EMR patients and a 'Green Plus' status for bile reflux and stomal ulceration patients.

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Betesil® (Betamethasone valerate0.1% medicated Plaster)			✓	**Decision:** 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.
3) New formulations & extensions to use				
Subcutaneous vedolizumab	✓ RED			Approved for gastroenterology indications where an anti TNF was deemed clinically inappropriate and self-administration was deemed beneficial for the patient.
4) NHS England Specialised Services communications noted and endorsed by APC				
SSC2117 - Specialised Commissioning Update February to April				The formulary will reflect the SSC position
SSC2119 - Not for Routine Commissioning Policy for Telotristat for treating carcinoid syndrome diarrhoea in adults				The formulary will reflect the SSC position
SSC2122 - Human plasma derived C1 esterase inhibitors for Hereditary Angioedema				The formulary will reflect the SSC position
SSC2125 - NICE Technology Appraisal Final Appraisal Determination - Lenalidomide with rituximab for previously treated follicular lymphoma				The formulary will reflect the SSC position
SSC2126 - Specialised Commissioning Update March 2020				The formulary will reflect the SSC position
SSC2128 - Two drug regimen policies for the treatment of HIV-1 Dolutegravir rilpivirine and dolutegravir lamivudine				The formulary will reflect the SSC position
SSC2129 - NICE Technology Appraisal Final Appraisal Determination - Pembrolizumab for previously treated advanced or metastatic urothelial cancer (CDF review TA519)				The formulary will reflect the SSC position
SSC2130 - Mercaptamine hydrochloride viscous eye drops for corneal cystine deposits in people aged older than 2 years				The formulary will reflect the SSC position
EAMS approval for remdesivir in COVID-19 https://www.gov.uk/government/news/mhra-supports-the-use-of-remdesivir-as-the-first-medicine-to-treat-covid-19-in-the-uk?utm_source=4307a5df-53f5-408b-bcf6-fcd2adddd655&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate				The formulary will reflect the SSC position
SSC2133 NICE Technology Appraisal Final Appraisal Determination - obinutuzumab with bendamustine for treating follicular lymphoma after rituximab				The formulary will reflect the SSC position
SSC2134 NICE Technology Appraisal Final Appraisal Determination: lorlatinib for previously treated ALK-positive advanced non-small-cell lung cancer				The formulary will reflect the SSC position
SSC2136 Clinical Commissioning Policy: Temozolomide as adjuvant treatment for people with newly diagnosed anaplastic astrocytoma without 1p/19q codeletion following surgery and radiotherapy (Adults)				The formulary will reflect the SSC position
SSC2137 Clinical Commissioning Policy: Dexrazoxane for preventing cardiotoxicity in children and young people (< 25 years) receiving high-dose anthracyclines or related drugs for the treatment of cancer				The formulary will reflect the SSC position

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SSC2138 Specialised Blood Disorder Policies: Factor X and Vonicog Alfa				The formulary will reflect the SSC position
SSC2139 NICE Technology Appraisal Final Appraisal Determination: larotrectinib for treating NTRK fusion-positive solid tumours				The formulary will reflect the SSC position
SSC2140 Canakinumab for periodic fever syndromes (all ages)				The formulary will reflect the SSC position
SSC2143 NICE Technology Appraisal Final Appraisal Determination: atezolizumab with nab-paclitaxel for treating PD-L1-positive, triple-negative, advanced breast cancer				The formulary will reflect the SSC position
SSC2144 - NICE Technology Appraisal Final Appraisal Determination - atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer				The formulary will reflect the SSC position
SSC2148 - Nivolumab as monotherapy treatment of adult patients with unresectable advanced, recurrent or metastatic oesophageal, squamous cell carcinoma (OSCC) after one prior fluoropyrimidine and platinum-based chemotherapy				The formulary will reflect the SSC position
5) Products considered by NICE				
TA617 Lusutrombopag for treating thrombocytopenia in people with chronic liver disease needing a planned invasive procedure				The formulary will reflect the NICE position
TA618 Atezolizumab with carboplatin and nab-paclitaxel for untreated advanced non-squamous non-small-cell lung cancer (terminated appraisal)				The formulary will reflect the NICE position
TA619 Palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer				The formulary will reflect the NICE position
TA620 Olaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer				The formulary will reflect the NICE position
TA621 Osimertinib for untreated EGFR mutation-positive non-small-cell lung cancer				The formulary will reflect the NICE position
TA622 Sotagliflozin with insulin for treating type 1 diabetes				The formulary will reflect the NICE position
TA623 Patiromer for treating hyperkalaemia				The formulary will reflect the NICE position
TA624 Peginterferon beta-1a for treating relapsing–remitting multiple sclerosis				The formulary will reflect the NICE position
TA625 Recombinant human parathyroid hormone for treating hypoparathyroidism (terminated appraisal)				The formulary will reflect the NICE position
TA626 Avatrombopag for treating thrombocytopenia in people with chronic liver disease needing a planned invasive procedure				The formulary will reflect the NICE position
TA627 Lenalidomide with rituximab for previously treated follicular lymphoma				The formulary will reflect the NICE position
TA628 Lorlatinib for previously treated ALK-positive advanced non-small-cell lung cancer				The formulary will reflect the NICE position
TA629 Obinutuzumab with bendamustine for treating follicular lymphoma after rituximab				The formulary will reflect the NICE position
TA630 Larotrectinib for treating NTRK fusion-positive solid tumours				The formulary will reflect the NICE position
TA631 Fremanezumab for preventing migraine				The formulary will reflect the NICE position

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TA632 Trastuzumab emtansine for adjuvant treatment of HER2-positive early breast cancer		The formulary will reflect the NICE position
TA633 Ustekinumab for treating moderately to severely active ulcerative colitis		The formulary will reflect the NICE position
TA634 Daratumumab with lenalidomide and dexamethasone for untreated multiple myeloma (terminated appraisal)		The formulary will reflect the NICE position
TA635 Ramucirumab with erlotinib for untreated EGFR-positive metastatic non-small-cell lung cancer (terminated appraisal)		The formulary will reflect the NICE position
TA636 Eculizumab for treating refractory myasthenia gravis (terminated appraisal)		The formulary will reflect the NICE position
TA637 Ranibizumab for treating diabetic retinopathy (terminated appraisal)		The formulary will reflect the NICE position
TA638 Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer		The formulary will reflect the NICE position
TA639 Atezolizumab with nab-paclitaxel for untreated PD-L1-positive, locally advanced or metastatic, triple-negative breast cancer		The formulary will reflect the NICE position
6) Northern (NHS) Treatment Advisory Group (N-TAG)		
Voke® Inhaler Nicotine Replacement Therapy for Smoking Cessation		The formulary will reflect the N – TAG position
Sativex® for the treatment of non-MS pain		The formulary will reflect the N – TAG position
Transcutaneous vagus nerve stimulation for treatment of cluster headache and migraine		Noted
Lycra Garments for the management of cerebral palsy and other neurological or musculoskeletal conditions		The formulary will reflect the N – TAG position
Infliximab Subcutaneous (Remsima®)		The formulary will reflect the N – TAG position
Verteporfin (Visudyne®) with photo-dynamic therapy for chronic central serous chorioretinopathy		The formulary will reflect the N – TAG position
Vaginal devices for female urinary stress incontinence		The formulary will reflect the N – TAG position
Purewick® female external urinary catheter		The formulary will reflect the N – TAG position
7) Regional Medicines Optimisation Committee (RMOC)		
Advisory Statement: Standard Principles for Medicines Prior Approval Forms (January 2020)		Noted.
Advisory Statement Sequential Use of Biologic Medicines (January 2020)		Noted.
Free of Charge (FOC) Medicines Schemes: Updated RMOC Advice for adoption as local policy (January 2020)		Noted.
8) Appeals against earlier decisions by the APC		
None		
9) Guidelines approved/retired. http://www.northoftyneapc.nhs.uk/guidance/		
Dexamfetamine shared care guideline		Approved
North of Tyne recommendations for symptom management in renal patients (including symptom management at the end of life)		Approved
Cinacalcet shared care guideline - update		Approved
Catheter formulary		Approved

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Vitamin D quick reference guide – update				Approved
Brand name prescribing – update				Approved
Ketamine in palliative care – update				Approved
Vitamin B12 guidance – update				Approved
Menopause guidance				Retired as NICE have now produced guidance
10) Miscellaneous decisions by the APC				
Sativex for MS spasticity – status				Sativex for MS spasticity is recommended by NICE. The guideline states that a shared care agreement should be in place. The MS team will initiate treatment, review response after 4 weeks (using a VAS score) and perform an annual review thereafter. A short shared care guideline should be produced that contains information regarding: • the clinical criteria for initiation • the requirement for a review by the MS team prior to transfer to the GP • the requirement for specialist annual review thereafter. **Decision** The committee agreed that Sativex for MS spasticity should be given an 'Amber' status once the SCG is approved. Until then prescribing will be retained in secondary care.
Ingenol mebutate				Following a series of safety alerts ingenol mebutate has lost its market authorisation and will therefore be removed from formulary.
Silicone scar preparations				The committee clarified that the use of silicone scar gel preparations was previously approved for use by the 'Burns Team and Scar Clinic' and the formulary will be amended to reflect this. Currently the formulary only states "burns team".
GLP-1 agonist RAG status				Clarity has been requested around the RAG status of GLP-1 agonists as some have a 'Green' status while other have a 'Green Plus' status. The committee agreed that the RAG status of all GLP1 drugs on formulary should be changed to 'Green' subject to local guidelines being followed.