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 19 th October 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.

1) Requests deferred from previous meetings

Product	Approved	Refused	Deferred	Notes
None				

2) New Requests

Product	Approved	Refused	Deferred	Notes
Cefazolin 1g & 2g Vials for injection	✓ R			Cefazolin has been requested as an alternative to flucloxacillin in patients with non-immediate penicillin allergy or in those who can't tolerate flucloxacillin or the alternatives. It is a first-generation cephalosporin with good activity against staphylococcus. Low quality evidence from fairly large cohort studies suggest cefazolin is of similar efficacy to flucloxacillin with no safety concerns. **Decision:** cefazolin will be added to the formulary as a RED drug. To be used on the advice of microbiology and ID physicians only.

Plenvu®	✓ R			Plenvu® is a lower volume (2 litres) alternative to Moviprep® (4 litres) for bowel cleansing prior to colonoscopy. The available evidence suggests Plenvu® is non-inferior to Moviprep® in terms of successful bowel cleansing. Plenvu® is intended to be used as a second line option as it is still slightly more expensive than Moviprep®, which makes a difference given the large quantities of the product that are used. Clinicians locally have reported that efficacy in cleansing seems comparable in use to Moviprep®, not better. Plenvu® will therefore be reserved for patients where large volumes of fluid load are a clinical problem. **Decision:** Plenvu® is approved as a second line option for bowel cleansing prior to colonoscopy.
Acarizax® oral lyophilisate	✓ R			Acarizax has been requested as a treatment for dust mite allergy. It is a licensed alternative to Oralvac. The group noted that the evidence, particularly in relation to total combined rhinitis score, wasn't particularly persuasive but it was more persuasive in terms of reducing the risk of moderate to severe asthma exacerbation. It was recognised that a licensed product should be used in preference to an unlicensed preparation. **Decision:** Acarizax® oral lyophilizate will be added to the formulary, as a RED drug, for use by immunology only.
Insulin aspart (Fiasp®)	✓ G			Insulin aspart (Fiasp®**)** is an ultra-fast, short acting insulin that can be injected close to mealtimes which increases flexibility for the patients. It is non-inferior to insulin aspart (NovoRapid®) in terms of change in HbA1 from baseline. It is available in 100units/ml pre-filled pen, cartridge and vials. The application was supported by diabetes specialists across the APC footprint. **Decision:** Insulin aspart (Fiasp®)will be added to the formulary as a GREEN drug.

Insulin Lispro (Lyumjev®)		✓		**Insulin Lispro** (Lyumjev®) is an ultra-fast, short acting insulin that can be injected close to mealtimes which increases flexibility for the patients. It is non-inferior to insulin lispro (Humalog®) in terms of change in HbA1 from baseline. Specialists at NHCFT and NUTH questioned the need for both Lyumjev® and Fiasp® on formulary. Lyumjev® is available in 2 different strengths (100 units/ml and 200 units/ml). One presentation is called "KwikPen Junior" despite not being licensed for children. **Decision:** The application for Insulin lispro (Lyumjev®) was refused on the grounds that the application wasn't supported as widely as the Fiasp® application, there were some slight concerns around the risk from the high strength formulation and the committee felt that there was a small risk of inadvertent prescribing in children.
Incliseran	✓ G			Approved for use in line with the NICE TA

3) New formulations & extensions to use

Product	Approved	Refused	Deferred	Notes
Olanzapine pamoate monohydrate 210mg, 300mg and 405mg injection (Zypadhera®)	✓ R			**Olanzapine Long-Acting Injection (Zypadhera®)** has been requested for the treatment of schizophrenia in adults within secure psychiatric services. In patients with schizophrenia olanzapine long-acting injection is non-inferior compared to oral olanzapine in terms of preventing exacerbations. The risk of post injection syndrome requires that patients are monitored for 3 hours after injection. CNTW plan to set a specific clinic for the post injection monitoring if approved. **Decision: O**lanzapine LA injection (Zypadhera®) was approved, for use in secure psychiatric services only, as a RED drug.

Quetiapine liquid	✓ R			Quetiapine has been requested as an antipsychotic for the treatment of moderate to severe manic episodes in bipolar disorder. It is requested for short term use only to allow stabilisation in acutely unwell bipolar patients with florid symptoms. This is with regular review and transfer to oral/depot medication as appropriate. **Decision:** Quetiapine liquid was approved for use in CNTW only, as a RED drug.
Fidaxomicin	✓ G+			Updated NICE guidance for the treatment of *C.difficile* has changed the role of fidaxomicin. The committee approved a status change to GREEN plus to allow GPs to prescribe (on the recommendation of a microbiologist).

4) NHS England Specialised Services communications noted and endorsed by APC

SSC2269: Rituximab for Immunobullous Disease (Ocular Amendment)	The formulary will reflect the SSC position
SSC2270: Abatacept for treatment of severe treatment-resistant morphoea (localised scleroderma) (adults and children 2 years and over)	The formulary will reflect the SSC position
SSC2272: Early Access to Medicines Scheme – tepotinib as monotherapy for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.	The formulary will reflect the SSC position
SSC2273: Mercaptamine hydrochloride viscous eyedrops for corneal cystine deposits in people aged 2 years and over	The formulary will reflect the SSC position
SSC2274: Baricitinib for use in monogenic interferonopathies (adults and children 2 years and over	The formulary will reflect the SSC position
SSC2278: pemigatinib for treating relapsed or refractory advanced cholangiocarcinoma with FGFR2 fusion or rearrangement	The formulary will reflect the SSC position
SSC2280 - NICE Technology Appraisal Final Appraisal Determination: abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy	The formulary will reflect the SSC position
SSC2282 - NICE Technology Appraisal Final Appraisal Determination - Midostaurin for treating advanced systemic mastocytosis	The formulary will reflect the SSC position
SSC2284 - Early Access to Medicines Scheme – nivolumab as monotherapy for the treatment of advanced or recurrent gastric or gastro-oesophageal junction cancer.	The formulary will reflect the SSC position
SSC2287 - NICE Technology Appraisal Final Appraisal Determination: apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer	The formulary will reflect the SSC position
SSC2288 - NICE Technology Appraisal Final Appraisal Determination: apalutamide with androgen deprivation therapy for treating high-risk hormone-relapsed non-metastatic prostate cancer.	The formulary will reflect the SSC position
SSC2289 - NICE Technology Appraisal Final Appraisal Determination: nivolumab for treating recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based chemotherapy.	The formulary will reflect the SSC position
SSC2290 - NICE Technology Appraisal Final Appraisal Determination: pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced oesophageal and gastro-oesophageal junction cancer.	The formulary will reflect the SSC position

SSC2291- NICE Technology Appraisal Consultation Document: Pembrolizumab for treating relapsed or refractory classical Hodgkin lymphoma after stem cell transplant or at least 2 previous therapies	The formulary will reflect the SSC position

5) Products considered by NICE

NICE reference	Formulary position	RAG status
HST15 Onasemnogene abeparvovec for treating spinal muscular atrophy	The formulary will reflect the NICE position	R
TA712 Enzalutamide for treating hormone-sensitive metastatic prostate cancer	The formulary will reflect the NICE position	R
TA713 Nivolumab for advanced non-squamous non-small-cell lung cancer after chemotherapy	The formulary will reflect the NICE position	R
TA714 Dasatinib for treating Philadelphia-chromosome-positive acute lymphoblastic leukaemia	Terminated appraisal	
TA715 Adalimumab, etanercept, infliximab and abatacept for treating moderate rheumatoid arthritis after conventional DMARDs have failed	The formulary will reflect the NICE position	R
TA716 Nivolumab with ipilimumab for previously treated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency	The formulary will reflect the NICE position	R
TA717 Duvelisib for treating relapsed follicular lymphoma after 2 or more systemic therapies	Terminated appraisal	
TA718 Ixekizumab for treating axial spondyloarthritis	The formulary will reflect the NICE position	R
TA719 Secukinumab for treating non-radiographic axial spondyloarthritis	The formulary will reflect the NICE position	R
TA720 Chlormethine gel for treating mycosis fungoides-type cutaneous T-cell lymphoma	The formulary will reflect the NICE position	R
TA721 Abiraterone for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer	The formulary will reflect the NICE position	R
TA722 Pemigatinib for treating relapsed or refractory advanced cholangiocarcinoma with FGFR2 fusion or rearrangement	The formulary will reflect the NICE position	R
TA723 Bimekizumab for treating moderate to severe plaque psoriasis	The formulary will reflect the NICE position	R
TA724 Nivolumab with ipilimumab and chemotherapy for untreated metastatic non-small-cell lung cancer	Negative appraisal	
TA725 Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy	The formulary will reflect the NICE position	R
TA726 Daratumumab with pomalidomide and dexamethasone for treating relapsed or refractory multiple myeloma	Terminated appraisal	
TA727 Isatuximab with carfilzomib and dexamethasone for treating relapsed or refractory multiple myeloma	Terminated appraisal	
TA728 Midostaurin for treating advanced systemic mastocytosis	The formulary will reflect the NICE position	R
TA729 Sapropterin for treating hyperphenylalaninaemia in phenylketonuria	The formulary will reflect the NICE position	R
TA730 Avapritinib for treating unresectable or metastatic gastrointestinal stromal tumours	Terminated appraisal	
TA731 Vericiguat for treating chronic heart failure with reduced ejection fraction	Terminated appraisal	
TA732 Baloxavir marboxil for treating acute uncomplicated influenza	Terminated appraisal	
TA733 Inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia	The formulary will reflect the NICE position	G
TA734 Secukinumab for treating moderate to severe plaque psoriasis in children and young people	The formulary will reflect the NICE position	R

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

Lurasidone (Latuda®) for the treatment of schizophrenia in adults and adolescents aged 13 years and over	✓ G+	Updated recommendation recommending use as an option as per criteria specified in recommendation, and also including use in adolescents. The formulary will reflect the N – TAG position. The APC agreed that lurasidone will have green plus formulary status.
Daily vs on-demand PDE-5 inhibitors for management of erectile dysfunction following treatment for prostate cancer		Updated recommendation that once daily oral 5mg tadalafil may be considered as an option for the management of erectile dysfunction following treatment for prostate cancer. Oral 2.5mg tadalafil is not recommended by NTAG for this indication based on cost. The formulary will reflect the N – TAG position.
Buprenorphine prolonged release injection for opioid dependence		New recommendation that these products offer an alternative option for the management of opioid dependence after oral methadone and/or oral buprenorphine. The formulary subcommittee will approve the specific product to be used locally following discussion with appropriate clinicians.

7) Regional Medicines Optimisation Committee (RMOC)

No new guidance published

8) Appeals against earlier decisions by the APC

Product	Approved	Refused	Deferred	Notes
None				

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

Methylphenidate SCG	New guideline for use of methylphenidate secondary to brain injury
Continence product formulary	
Catheter formulary	
SGLT-2 in diabetes top tips document	Diabetes clinical network guidance to be hosted on APC website until March 2023, or until superseded by new evidence
IMD Guidelines	Review date extended to March 2022

10) Miscellaneous decisions by the APC

Codeine 15mg tablets	Codeine 15mg to be made first line formulary choice, with 30mg still available as a second line choice