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 5th April 2022.**

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
Buprenorphine prolonged-release injection (Buvidal®)	✓ R			Buprenorphine prolonged-release injection (Buvidal®) is a long acting buprenorphine preparation for the treatment of opioid dependence when used within a framework of medical, social and psychological treatment. It allows weekly or monthly injections therefore avoiding the need for daily supervised visits. Treatment is intended for use in adults and adolescents aged 16 years or over in accordance with RMOC and NTAG guidance including some criteria relating to the communication and documentation of use to avoid inadvertent overdose or patients deliberately seeking out extra doses.
Chloroprocaine 10mg/ml & 20mg/ml (Ampres®	✓ R			Chloroprocaine 10mg/ml & 20mg/ml has been requested for use in spinal nerve and peripheral blocks on the grounds that it is a shorter acting anaesthetic, which allows discharge of patients quicker. Due to its short duration of action it was felt it would have a very niche role. Approval was given but will be reviewed on receipt of an audit one year after approval.

Intra-ocular triamcinolone 40mg/ml Intracinol & Triesence	Intracinol ✓ R	Triesence ✓		Triesence and Intracinol are preparations of triamcinolone 40mg/ml for intra-ocular use both of which are preservative free. The preservative in Kenalog® (benzyl alcohol) is thought to be associated with serious adverse effects. Intracinol® is licensed in the UK as a medical device whereas Triesence® is an unlicensed import from the USA. The Triesence preparation is also significantly more expensive than the Intracinol and is not currently available for import. Intracinol is on the Moorfields Formulary. The committee approved the formulary inclusion of Intracinol but refused the addition of Triesence

3) New formulations & extensions to use

Product	Approved	Refused	Deferred	Notes
None				

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

SSC2323 NICE Technology Appraisal Final Appraisal Determination: daratumumab in combination for untreated multiple myeloma when a stem cell transplant is suitable.	The formulary will reflect the SSC position
SSC2324 NICE Technology Appraisal Final Appraisal Determination: pembrolizumab with carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer.	The formulary will reflect the SSC position
SSC2325 Specialised Commissioning update on future NICE Appraisals that are due to be commissioned during January 2022 to March 2022.	The formulary will reflect the SSC position
SSC2326 NICE Technology Appraisal Guidance: Risdiplam for treating spinal muscular atrophy.	The formulary will reflect the SSC position
SSC2329 NICE Technology Appraisal Final Appraisal Determination: 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
SSC2333 Early Access to Medicines Scheme – asciminib indicated for the treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) without T315I mutation previously treated with two or more tyrosine kinase inhibitors.	The formulary will reflect the SSC position
SSC2334: National Orbis Drug Access Arrangements – atezolizumab monotherapy for adjuvant treatment following complete resection for adult patients with Stage II to IIIA (7th edition of the UICC/AJCC-staging system) non-small cell lung cancer whose tumours have PD-L1 expression on ≥ 50% of tumour cells and whose disease has not progressed following platinum-based adjuvant chemotherapy	The formulary will reflect the SSC position
SSC2335: Palivizumab passive immunisation against Respiratory Syncytial Virus (RSV) in at-risk pre-term infants (2021/22 Season)	The formulary will reflect the SSC position
SSC2336: Early Access to Medicines Scheme – asciminib indicated for the treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) without T315I mutation previously treated with two or more tyrosine kinase inhibitors	The formulary will reflect the SSC position
SSC2337: NICE Technology Appraisal Guidance: Crizanlizumab for preventing sickle cell crises in sickle cell disease (TA743)	The formulary will reflect the SSC position
SSC2338: NICE Technology Appraisal Guidance: Inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia (TA733)	The formulary will reflect the SSC position

SSC2339: Early Access to Medicines Scheme – Voxelotor in the treatment of haemolytic anaemia due to sickle cell disease (SCD) in adults and paediatric patients 12 years of age and older as monotherapy or in combination with hydroxycarbamide	The formulary will reflect the SSC position
SSC2340 NICE TA FAD: nivolumab with ipilimumab for untreated advanced renal cell carcinoma	The formulary will reflect the SSC position
SSC2341 is regarding NICE Technology Appraisal: Nintedanib for treating progressive fibrosing interstitial lung diseases (TA747).	The formulary will reflect the SSC position
SSC2342 is a Specialised Commissioning Update on future NICE Appraisals that are due to be commissioned during April 2022 to May 2022.	The formulary will reflect the SSC position
SSC2343 NICE Technology Appraisal: dostarlimab for previously treated advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency	The formulary will reflect the SSC position
SSC2348 NICE Technology Appraisal Final Appraisal Determination: tucatinib with trastuzumab and capecitabine for treating HER2-positive advanced breast cancer after 2 or more anti-HER2 therapies.	The formulary will reflect the SSC position
SSC2351 NICE Technology Appraisal sotorasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer.	The formulary will reflect the SSC position

5) Products considered by NICE

NICE reference	Formulary position	RAG status
HST17 Odevixibat for treating progressive familial intrahepatic cholestasis – highly specialised technologies	The formulary will reflect the NICE position	R
TA759 Fostamatinib for treating refractory chronic immune thrombocytopenia Negative appraisal	The formulary will reflect the NICE position	N/A
TA760 Selpercatinib for previously treated RET fusion-positive advanced non-small-cell lung cancer.	The formulary will reflect the NICE position	R
TA761 Osimertinib for adjuvant treatment of EGFR mutation-positive non-small-cell lung cancer after complete tumour resection	The formulary will reflect the NICE position	R
TA762 Olaparib for treating BRCA mutation-positive HER2-negative metastatic breast cancer after chemotherapy (terminated appraisal)	The formulary will reflect the NICE position	N/A
TA763 Daratumumab in combination for untreated multiple myeloma when a stem cell transplant is suitable	The formulary will reflect the NICE position	R
TA764 Fremanezumab for preventing migraine	The formulary will reflect the NICE position	R
TA765 Venetoclax with azacitidine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable	The formulary will reflect the NICE position	R
TA766 Pembrolizumab for adjuvant treatment of completely resected stage 3 melanoma	The formulary will reflect the NICE position	R
TA767 Ponesimod for treating relapsing–remitting multiple sclerosis	The formulary will reflect the NICE position	R
TA768 Upadacitinib for treating active psoriatic arthritis after inadequate response to DMARDs	The formulary will reflect the NICE position	R
TA769 Palforzia for treating peanut allergy in children and young people	The formulary will reflect the NICE position	R
TA770 Pembrolizumab with carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer	The formulary will reflect the NICE position	R
TA771 Daratumumab with bortezomib, melphalan and prednisone for untreated multiple myeloma (terminated appraisal)	The formulary will reflect the NICE position	N/A
TA772 Pembrolizumab for treating relapsed or refractory classical Hodgkin lymphoma after stem cell transplant or at least 2 previous therapies	The formulary will reflect the NICE position	R
TA773 Empagliflozin for treating chronic heart failure with reduced ejection fraction	The formulary will reflect the NICE position	G+
TA774 Lenalidomide for relapsed or refractory mantle cell lymphoma (terminated appraisal)	The formulary will reflect the NICE position	R
TA775 Dapagliflozin for treating chronic kidney disease	The formulary will reflect the NICE position	G

TA776 Pitolisant hydrochloride for treating excessive daytime sleepiness caused by obstructive sleep apnoea - negative appraisal.	The formulary will reflect the NICE position	**N/A**
TA777 Solriamfetol for treating excessive daytime sleepiness caused by obstructive sleep apnoea - Negative appraisal	The formulary will reflect the NICE position	**N/A**
TA778 Pegcetacoplan for treating paroxysmal nocturnal haemoglobinuria	The formulary will reflect the NICE position	R
TA779 Dostarlimab for previously treated advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency	The formulary will reflect the NICE position	R

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

i-Port Advance® for use in children and adults with Type 1 diabetes - reviewed & no changes made	The formulary will reflect the N – TAG position
Infliximab subcutaneous injection (Remsima SC ®)- reviewed & no changes made	The formulary will reflect the N – TAG position
Actipatch® for management of localised musculoskeletal pain - reviewed & no changes made.	The formulary will reflect the N – TAG position
Alfapump® device for ascites due to liver cirrhosis pain - reviewed & no changes made.	The formulary will reflect the N – TAG position
Pitolisant (Wakix®) for the treatment of narcolepsy with or without cataplexy in adults - updated to reference NICE TA for Solriamfetol	The formulary will reflect the N – TAG position
Ulipristal (EllaOne®) for post-coital contraception: Updated data concerning the effect of body weight (BMI) on efficacy of both levonorgestegel and ulipristal products	The formulary will reflect the N – TAG position

7) Regional Medicines Optimisation Committee (RMOC)

No publications

8) Appeals against earlier decisions by the APC

Product	Approved	Refused	Deferred	Notes
None				

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

Gluten Free Guidance – update approved.
Sativex in MS SCG – update approved.
Urology Guideline - update approved.
Melatonin deprescribing guideline – approved.
Clinical network Headache guidelines – update approved.
Vit B12 - update approved.
IMD guidance – expiry date extended
Diabetes Stepped Approach guideline Jan 2019 - replaced with link to NICE update NG28 Visual summary (nice.org.uk)

10) Miscellaneous decisions by the APC

Dapagliflozin 5mg tablets	The formulary entry will be updated to reflect the loss of licence for Type 1 diabetes.
TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia	RAG Status to be changed to from RED to Green plus to reflect the updated TAG
Estradiol 0.06% gel (Oestrogel®)	Formulary to be updated as not added when first approved

Formulary review – inhalers

The main purpose of the review was to encourage the use of dry powder inhalers (DPI) over pressurised metered dose inhalers (pMDI). The propellants used in pMDIs have a high carbon footprint. DPIs are now first choice for all of the different inhaler classes.

Note: DPIs unless stated

SABA	Comment
Salbutamol Easyhaler®	First Choice*
Salbutamol Accuhaler®	Alternative First Choice*
Terbutaline Turbohaler®	To remain on Formulary*
Salbutamol generic – pMDI**	
Airomir® Autohaler – pMDI	
Salamol® Easi-breathe - pMDI	Alternative for patients hypersensitive to lactose or milk protein

LABA	Comment
Formoterol Turbohaler®	First choice *
Salmeterol Accuhaler®	Second choice*
Salmeterol – pMDI	Third choice*

LAMA	Comment
Glycopyronnium (Seebri Breezhaler®)	These inhalers have the same weight on the formulary
Umeclidinium (Incruse Ellipta®)	
Aclidinium (Eklira Genuair®)	
Tiotropium (Handihaler®)	For existing COPD patients only and those unable to use the other LAMA devices. Consideration should be given to switching at next review, providing adequate training / counselling is provided in device use
Tiotropium (Respimat®) - pMDI	Asthma: Step 4 of BTS/SIGN guidelines. Treatment should be stopped if not effective.

LABA/LAMA	Comment
Glycopyronium/indacaterol (Ultibro Breezhaler®)	First Choice
Umeclidinium/vilanterol (Anoro Ellipta®)	Second Choice
Aclidinium/formoterol (Duaklir Genuair®)	Alternative Second Choice
Glycopyrronium/formoterol (Bevespi Aerosphere® - pMDI) **NEW**	Add as First Choice pMDI*
Tiotropium/olodaterol (Spiolto Respimat® - pMDI)	Second choice pMDI*

ICS	Comment
Budesonide Easyhaler®	First choice*
Budesonide Turbohaler®	Alternative First Choice*
Beclometasone Easyhaler®	Second Choice*
Beclometasone QVAR® Easibreath - pMDI	Remove from formulary*
Beclometasone QVAR® - pMDI	
Beclometasone QVAR® Autohaler - pMDI	
Beclometasone Clenil Modulite® - pMDI**	Third choice

ICS/LABA	Comment
Budesonide/formoterol (DuoResp Spiromax®)	First Choice
Budesonide/formoterol (Symbicort Turbohaler®)	First Choice - Second line
Fluticasone furoate/vilanterol (Relvar Ellipta®)	Second Choice
Beclometasone/formoterol (Fostair® Nexthaler)	Third Choice
Fluticasone/Salmeterol (Seretide Accuhaler®)	Remove*
Beclometasone/formoterol (Fostair®) **pMDI**	First Choice pMDI*
Beclometasone/formoterol (Luforbec®) **pMDI NEW**	This is equivalent to the Fostair pMDI - agreed to add as an option*
Fluticasone/Salmeterol (Flutiform®)	Remove from formulary*
Fluticasone/Salmeterol (Flutiform K inhaler®) **NEW**	Not to be added to formulary*
Mometasone/Indacaterol (Atectura Breezhaler®) **NEW**	Add to formulary - ***Asthma only****

ICS/LABA/LAMA	Comment
Fluticasone furoate/Vilanterol/Umeclidinium (Trelegy Ellipta®)	First Choice
Beclometasone dipropionate/ Formoterol/ Glycopyrronium (Trimbow® NEXThaler) **NEW**	Add to formulary - Second Choice*
Budesonide/Formoterol/glycopyronnium (Trixeo Aerosphere® pMDI) **NEW**	Add to formulary as First Choice pMDI*
Beclometasone dipropionate/ Formoterol/ Glycopyrronium Trimbow®) **pMDI**	Second Choice pMDI*
Mometasone furoate/indacaterol/ glycopyrronium bromide (Enerzair Breezhaler®) **NEW**	Add to formulary - ***Asthma only****

***New recommendation**

**** to support patients with inspiratory effort insufficient for DPIs and/ or reduce local oral mucosal side effects – preferably should be used with a spacer**