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 July 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
Clofazimine 50 mg and 100 mg capsules	✓ R			Clofazimine has been requested for the treatment of non-tuberculous mycobacterial (NTM) infections, on the advice of microbiology and Infectious Diseases (ID) physicians. It was noted that the evidence base for clofazimine in NTM infections is weak but was also recognised that NTM infections are very challenging to treat, and that clofazimine is relatively inexpensive. **Decision:** Approved Clofazimine will be added to the formulary, as a red drug, for use on the advice of microbiology or ID physicians.
Eloine® (20 mcg ethinylestradiol and 3 mg drospirenone)			✓ G	This is a combined oral contraceptive (COC) similar to Yasmin® but with a lower ethinylestradiol dose and with a 4-day pill free window. It has been requested on the grounds of evidence for improvement in premenstrual syndrome/premenstrual dysphoric disorder and acne. The FSRH reviewed Eloine® and concluded it is of comparable contraceptive effectiveness to other COCs. **Decision: Deferred** The Formulary Subcommittee have asked for clarification of the positioning of Eloine® compared to Yasmin® and whether there is a need for both agents on the Formulary.

Cangrelor 50mg vials (Kengrexal®)	✓ R			Cangrelor has been requested for bridging therapy in patients who have recently had a coronary stent but require urgent elective surgery. To avoid major bleeding oral antiplatelet agents need to be stopped 5-7 days before surgery, increasing the risk of stent thrombosis. Cangrelor is a short acting antiplatelet agent, administered by IV infusion, started once the oral antiplatelet agent is stopped and continued until a short period before the procedure. The American College of Cardiology (ACC) suggest that cangrelor is used as the first-line agent for perioperative bridging while the evidence base for bridging is still developing. **Decision:** Approved Cangrelor will be added to the formulary, as a Red drug
Otigo® ear drops (Phenazone 40mg/g with lidocaine 10mg/g)	✓ G			Otigo® ear drops (Phenazone 40mg/g with lidocaine 10mg/g) will be added to the formulary, in line with NICE, to support antimicrobial stewardship.

3) New formulations & extensions to use

Product	Approved	Refused	Deferred	Notes
Estradiol 1.53mg/spray transdermal spray (Lenzetto®)	✓ G			Suggested as an alternative to patches and gels for patients who have issues with absorption, find patch adhesive irritating or the gel messy. Offers flexibility for patients requiring low doses. More expensive than Sandrena® and Oestrogel® **Decision:** Approved
Estradiol 0.75mg/1.25g gel (Oestrogel®)	✓ G			Cheaper alternative to Sandrena® which is currently on the formulary **Decision:** Approved
Estradiol 10 microgram vaginal tablets (Vagirux®)	✓ G			An alternative to Vagifem®. Vagirux® is cheaper and has 1 reusable applicator per pack whereas Vagifem® uses 1 single use applicator per tablet. Therefore Vagirux® is more sustainable **Decision:** Approved
Micronised progesterone 100 mg capsules (Utrogestan®)	✓ G			Natural progesterone requested both for its licenced indication and off label use in conditions such as perimenopause, premature ovarian insufficiency, and adolescents undergoing pubertal induction following chemotherapy. It has less progestogenic and androgenic side effects, but less effective cycle control. Will be used as a second line agent. **Decision:** Approved

Testosterone gel (Testogel®/Testim®)	✓ G+			The RAG status of testosterone for the treatment of low sexual desire in menopausal women is currently Green Plus but this is problematic in areas without a specialist menopause clinic **Decision:** The committee agreed that the status should remain as Green Plus and that specialist involvement and agreement on appropriateness and monitoring via "Advice and Guidance" was enough to allow GPs to initiate.
Modafinil	✓ G+			Modafinil is psychostimulant for the treatment of narcolepsy. It has now been requested for treatment of idiopathic hypersomnia. Limited evidence suggests benefit in terms of increasing sleep latency and driving performance. The current status of modafinil, for narcolepsy, is Green Plus and there are no specific monitoring requirements Patients will remain under the care of the specialist sleep service but it was agreed that Green Plus was appropriate. **Decision:** Approved for idiopathic hypersomnia, as a Green Plus drug.
Rituximab	✓ R			Requested for autoimmune hepatitis in patients who have failed or who are intolerant of therapies such as azathioprine, mycophenolate mofetil, corticosteroids and tacrolimus. Limited evidence is available to support use but use via IFR in a limited number of patients locally has been successful in terms of normalising LFTs and reducing the use of other immunosuppressants. **Decision:** Approved for the treatment of autoimmune hepatitis, as a Red drug.
Capsaicin 0.025% cream	✓ G			Request submitted to change the current formulary status from Green Plus to Green in line with NICE osteoarthritis guidance. **Decision:** Approved
Dacepton® apomorphine (10mg/ml and 5mg/ml)	✓ A			A similar product to APO-go®, with a longer in-use expiry in the syringe driver/pump therefore leading to savings. **Decision:** Approved

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

SSC2352 NICE Technology Appraisal Final Appraisal Determination: daratumumab monotherapy for treating relapsed and refractory multiple myeloma	The formulary will reflect the SSC position
SSC2355 National procurement for antiretrovirals for HIV treatment and prevention (pre-exposure prevention (PrEP) and post-exposure prevention (PEP))	The formulary will reflect the SSC position

SSC2356 NICE Technology Appraisal Final Appraisal Determination: venetoclax with low dose cytarabine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable	The formulary will reflect the SSC position
SSC2358 NICE Technology Appraisal: cabotegravir with rilpivirine for treating HIV-1.	The formulary will reflect the SSC position
SSC2360 NICE Technology Appraisal Final Appraisal Determination: Avelumab for maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy	The formulary will reflect the SSC position
SSC2361 NICE Technology Appraisal Final Appraisal Determination: tepotinib for treating advanced non-small-cell lung cancer with MET gene alterations.	The formulary will reflect the SSC position
SSC2362 Early Access to Medicines Scheme – Lutetium (177Lu) vipivotide tetraxetan for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC).	The formulary will reflect the SSC position
SSC2364 Early Access to Medicines Scheme – Risankizumab for the treatment of adolescent patients aged 16 to 17 years with moderately to severely active Crohn's disease	The formulary will reflect the SSC position
SSC2371 NICE Technology Appraisal Final Appraisal Determination: ibrutinib for treating Waldenstrom's macroglobulinaemia (CDF review TA491).	The formulary will reflect the SSC position
SSC2372 NICE Technology Appraisal Final Appraisal Determination: venetoclax for treating chronic lymphocytic leukaemia.	The formulary will reflect the SSC position
SSC2373 is regarding National Orbis Drug Access Arrangements – mobocertinib for treating EGFR Exon 20 insertion-positive advanced non-small-cell lung cancer after platinum-based chemotherapy.	The formulary will reflect the SSC position
SSC2375 NICE Technology Appraisal Final Appraisal Determination: durvalumab for maintenance treatment of unresectable non-small-cell lung cancer after platinum-based chemoradiation.	The formulary will reflect the SSC position
SSC2379 NICE Technology Appraisal Final Appraisal Determination: cemiplimab for treating advanced cutaneous squamous cell carcinoma	The formulary will reflect the SSC position
SSC2380 NICE Technology Appraisal Final Appraisal Determination: pembrolizumab plus chemotherapy for untreated, triple-negative, locally recurrent unresectable or metastatic breast cancer.	The formulary will reflect the SSC position

5) Products considered by NICE

NICE reference	Formulary position	RAG status
HST18 Atidarsagene autotemcel for treating metachromatic leukodystrophy	The formulary will reflect the NICE position	R
HST19 Elosulfase alfa for treating mucopolysaccharidosis type 4A	The formulary will reflect the NICE position	R
HST20 Selumetinib for treating symptomatic and inoperable plexiform neurofibromas associated with type 1 neurofibromatosis in children aged 3 and over	The formulary will reflect the NICE position	R
TA780 Nivolumab with ipilimumab for untreated advanced renal cell carcinoma	The formulary will reflect the NICE position	R
TA781 Sotorasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer	The formulary will reflect the NICE position	R
TA782 Tagraxofusp for treating blastic plasmacytoid dendritic cell neoplasm	Terminated appraisal	n/a
TA783 Daratumumab monotherapy for treating relapsed and refractory multiple myeloma	The formulary will reflect the NICE position	R
TA784 Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer	The formulary will reflect the NICE position	R
TA785 Nivolumab with cabozantinib for untreated advanced renal cell carcinoma	terminated appraisal	n/a
TA786 Tucatinib with trastuzumab and capecitabine for treating HER2-positive advanced breast cancer after 2 or more anti-HER2 therapies	The formulary will reflect the NICE position	R

TA787 Venetoclax with low dose cytarabine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable	The formulary will reflect the NICE position	R
TA788 Avelumab for maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy	The formulary will reflect the NICE position	R
TA789 Tepotinib for treating advanced non-small-cell lung cancer with MET gene alterations	The formulary will reflect the NICE position	R
TA790 TYRX Absorbable Antibacterial Envelope for preventing infection from cardiac implantable electronic devices	Terminated appraisal	n/a
TA791 Romosozumab for treating severe osteoporosis	The formulary will reflect the NICE position	R
TA792 Filgotinib for treating moderately to severely active ulcerative colitis	The formulary will reflect the NICE position	R
TA793 Anifrolumab for treating active autoantibody-positive systemic lupus erythematosus	Terminated appraisal	n/a
TA794 Diroximel fumarate for treating relapsing–remitting multiple sclerosis	The formulary will reflect the NICE position	R
TA795 Ibrutinib for treating Waldenstrom's macroglobulinaemia	Negative appraisal	n/a
TA796 Venetoclax for treating chronic lymphocytic leukaemia	The formulary will reflect the NICE position	R
TA798 Durvalumab for maintenance treatment of unresectable non-small-cell lung cancer after platinum-based chemoradiation	The formulary will reflect the NICE position	R
TA799 Faricimab for treating diabetic macular oedema	The formulary will reflect the NICE position	R
TA800 Faricimab for treating wet age-related macular degeneration	The formulary will reflect the NICE position	R
TA801 Pembrolizumab plus chemotherapy for untreated, triple-negative, locally recurrent unresectable or metastatic breast cancer	The formulary will reflect the NICE position	R
TA802 Cemiplimab for treating advanced cutaneous squamous cell carcinoma	The formulary will reflect the NICE position	R
TA804 Teduglutide for treating short bowel syndrome	The formulary will reflect the NICE position	R

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

The following recommendations will be adopted across the APC area and the formulary will reflect the N – TAG position:

- NTAG Biosimilars Statement – new
- Budesonide orodispersible for maintenance treatment of eosinophilic oesophagitis – new
- iPORT advance – update
- Flash Glucose Monitoring – update
- NICE type 2 diabetes guidance
- Dapagliflozin in CKD Top Tips – new
- SGLT2 in Heart failure Top Tips – new
- SGLT2 in Type 2 Diabetes – update. Replaces version previously approved individually by APC
- DOAC for AF decision aid

7) Regional Medicines Optimisation Committee (RMOC)

No updates	

8) Appeals against earlier decisions by the APC

Product	Approved	Refused	Deferred	Notes
None				

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

Vit B12	Approved
Menopause guidelines	Approved
Hydroxychloroquine SCG	Approved

Lithium SCG	Update approved
IMDs	Expiry date extended to ed Sept

10) Miscellaneous decisions by the APC

Potassium permanganate	There has been a recent NPSA safety alert regarding inadvertent oral ingestion of potassium permanganate. There are several actions, many of which will be getting dealt with via the medication safety officer network. **Decision:** The Formulary will be updated to include the link to the NPSA safety alert along with the following specific statements: • **Not** to use issue potassium permanganate on repeat prescription. • Tablets will not be recommended for use
Neovaginal atresia following vaginoplasty – vaginal lubricants	Request from a gender dysphoria services to allow inclusion of lubricant preparations to help prevent neovaginal atresia following vaginoplasty. Work will be progressed with the specialist services in order to clarify the protocol for use of these products and that will then be included in the gender dysphoria guidance.
GPs with Extended Roles (GPwER)	The formulary currently refers to hospital specialists in the context of Green Plus drugs. To support GPwER's recommending these treatments it was agreed to change the statement to just say "specialists".
Inhaler choices for children	Further to the recent review of the inhaler section of the Formulary it has become apparent that there is a limited choice of inhalers suitable for use in children. The following additions are now approved: **ICS** • Clenil® MDI will remain 1st line choice • fluticasone MDI (Flixotide Evohaler®) will be added to the Formulary. **ICS/LABA** • **Combisal® MDI,** which is available in the same three strengths and indications as Seretide Evohaler® pMDI, provides significant potential cost savings for the NHS and will be added to the formulary.
Pregabalin use in pregnancy	The link to the MHRA alert will be added to the formulary entry. It was agreed that links to NPSA/MHRA alerts will be added to the formulary on a case-by-case basis and that a statement will be added to formulary to say that the formulary should not be considered the definitive resource for these alerts.