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 11th October 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 a specialist (hospital or GP with an extended role) but where the provision of additional information, or an information leaflet, may be appropriate to facilitate continuing treatment by GPs.
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**
Methoxyflurane 99.9% inhalation vapour (Penthrox®) – Trauma related pain	✓ R			Previously considered for trauma related pain in 2016 and refused on safety grounds. It was felt that these concerns had largely been addressed. The carbon footprint of Penthrox® is significantly lower than Entonox®. The application from QEH ED has support from NUTH, NCIC and NHCFT. It is currently on the County Durham and Tees Formulary and used by the North West Ambulance Service. **Decision:** Approved for trauma related pain in Emergency Departments, in adults only, as a RED drug.
Methoxyflurane 99.9% inhalation vapour (Penthrox®) – Procedural analgesia	✓ R			Requested instead of Entonox® for analgesia in procedures such as VAC dressing change/stent change/brachytherapy rod change. **Decision: Approved** for procedural analgesia in adult patients, as a RED drug
Tedizolid (Sivextro®)	✓ R			Newer antibiotic related to linezolid that is licensed for bacterial skin and skin structure infections. It has a shorter course length and lower risk of myelosuppression compared to linezolid. **Decision: Approved** for use on the advice of microbiologists / ID physicians, as a RED drug.

Estradiol valerate plus dienogest (Qlaira®)	✓ G+			This is a multiphasic combined oral contraceptive (COC) requested for women who need HRT as well as contraceptive pill, and for heavy menstrual bleeding (HMB). Requested as 2nd / 3rd line agent. **Decision: Approved** as a GREEN Plus drug.
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. The Formulary Subcommittee asked for clarification of the positioning of Eloine® compared to Yasmin® and whether there is a need for both agents on the Formulary. Subsequent correspondance confirmed that the 20mcg version is particularly useful in PMS and PMDD as many of these women struggle with hormones in general and the lower dose tends to be better tolerated. The specialist team agreed that Eloine® should replace Yasmin on the formulary and that Lucette® would be retained for contraception in women preferring a less androgenic combined pill. **Decision: Approved**
Estradot® patches	✓ G			Estradot patches are smaller, less irritating, more adherent and more cosmetically acceptable than alternatively available patches, whilst providing comparable serum oestradiol concentrations. Given the current shortages in estradiol topical gel, many women are temporarily having to be prescribed transdermal patches as an alternative. Many of these women use gel as they did not previously tolerate or find patches suitable. Given the smaller size of Estradot, they are likely to prefer Estradot as an alternative than larger patches. In cases where transdermal administration is appropriate, its adhesive technology offers a small patch size at the lower end of the cost range for transdermal patches. **Decision: Approved**

3) New formulations & extensions to use

Product	Approved	Refused	Deferred	Notes
Nebulised colistimethate & nebulised gentamicin for use in patients on assisted ventilation, patients with tracheostomies and those with persistent bacterial bronchitis.	✓ G+			Nebulised colistimethate & nebulised gentamicin are both are currently approved for use in bronchiectasis. This application is for an extension to use to patients on assisted ventilation, patients with tracheostomies and those with persistent bacterial bronchitis. **Decision: Approved**
Hydrocortisone modified release capsules (Efmody®)		✓		Requested for congenital adrenal hypoplasia. The EMA had stated that no claims on clinical superiority versus standard glucocorticoid therapy can be made for Efmody®. Efomdy® is expensive compared to immediate release hydrocortisone. It has previously also been rejected by the SMC on the grounds that the manufacturer did not present a sufficiently robust clinical and economic analysis to gain acceptance. **Decision: Refused.**
Melatonin (Adaflex®) tablets	✓ A			Adaflex® is a newly licensed immediate release melatonin preparation for insomnia in children from 6-17 years with ADHD. The request is to replace Circadin® on formulary for children and young people in line with currently approved indications. It is cheaper than Circadin® at some doses and significantly cheaper than Slenyto® **Decision: Approved** Adaflex® will be added to the formulary in place of Circadin® for children and young people in accordance with current formulary approvals for melatonin.
Midazolam 5mg/ml (7.5ml) (Miprosed®)	✓ R			NUTH currently use unlicensed 10mg/ml midazolam oral solution for sedation and pre-medication in children. Miprosed® is licensed for these indications and is significantly cheaper. **Decision: Approved** for sedation and pre-medication in children, as a RED drug.
Metformin (500mg oral powder sachets sugar free)	✓ G			Metformin (500mg oral powder sachets sugar free) will be added to the formulary as a more cost effective option than the 500mg/5ml oral solution sugar free. **Decision: Approved**

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

• SSC2400: NICE Technology Appraisal Final Appraisal Determination: asciminib for treating chronic myeloid leukaemia after 2 or more tyrosine kinase inhibitors	The formulary will reflect the SSC position
• SSC2401: Palivizumab passive immunisation against Respiratory Syncytial Virus (RSV) in at-risk infants (2022/23 Season)	The formulary will reflect the SSC position
• SSC2402: NICE Technology Appraisal Final Appraisal Determination: nivolumab for adjuvant treatment of invasive urothelial cancer at high risk of recurrence	The formulary will reflect the SSC position
• SSC2404: Early Access to Medicines Scheme – Efgartigimod alfa in the treatment of adult patients with AChR-antibody seropositive generalised myasthenia gravis (gMG),including patients with refractory gMG who have failed, not tolerated or are ineligible for licensed treatment.	The formulary will reflect the SSC position
• SSC2406: NICE Technology Appraisal Final Appraisal Determination: alpelisib with fulvestrant for treating hormone receptor-positive, HER2-negative, PIK3CA-mutated advanced breast cancer	The formulary will reflect the SSC position
• SSC2407: NICE Technology Appraisal Final Appraisal Determination: nivolumab with ipilimumab for untreated unresectable malignant pleural mesothelioma	The formulary will reflect the SSC position
• SSC2411: Specialised Commissioning update -NICE notification letter Jul-Oct	The formulary will reflect the SSC position
• SSC2412: HST20 Selumetinib NICE notification letter and Appendix A	The formulary will reflect the SSC position
• SSC2413: EAMS Voxelotor update letter to trusts	The formulary will reflect the SSC position
• SSC2414: NICE Technology Appraisal Consultation Document: lenvatinib with pembrolizumab for untreated advanced renal cell carcinoma	The formulary will reflect the SSC position
• SSC2415: NICE Technology Appraisal Final Appraisal Determination: atezolizumab for adjuvant treatment of resected non-small-cell lung cancer	The formulary will reflect the SSC position
• SSC2418: Specialised Commissioning Update Sept 22 and Table	The formulary will reflect the SSC position
• SSC2419: NHS England update on selected providers of Inherited White Matter Disorders Diagnostic and Management Service (IWMD) (All Ages)	The formulary will reflect the SSC position
• SSC2420: NICE Technology Appraisal Final Appraisal Determination: oral azacitidine for maintenance treatment of acute myeloid leukaemia after induction therapy	The formulary will reflect the SSC position
• SSC2423: NICE Technology Appraisal Final Appraisal Document: pembrolizumab for adjuvant treatment of renal cell carcinoma	The formulary will reflect the SSC position
• SSC2424: NICE Technology Appraisal: TA821: Avalglucosidase alfa in Pompe disease	The formulary will reflect the SSC position
• SSC2425: NICE Technology Appraisal TA804: Teduglutide for treating short bowel syndrome.	The formulary will reflect the SSC position
• SSC2427: NICE Technology Appraisal Final Appraisal Document: palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy	The formulary will reflect the SSC position
• SSC2428: NICE Technology Appraisal Final Appraisal Document: pembrolizumab for adjuvant treatment of resected stage 2B or 2C melanoma	The formulary will reflect the SSC position

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

Approval of NEELI-2 V2.	The APC website will be updated to point directly to this updated guidance.

6) Regional Medicines Optimisation Committee (RMOC)

Hydroxychloroquine and chloroquine retinopathy monitoring On behalf of the national Regional Medicines Optimisation Committees (RMOCs) system, RMOC (South) has developed practical recommendations for safe ophthalmology monitoring of patients who are receiving long term hydroxychloroquine or chloroquine. The document outlines the risks of retinopathy and sets out a structured approach for health professionals to manage these risks. The local services here are expanding capacity in services and therefore, until monitoring can be in line with the recommendations by the RCOphth local organisations should add this to their risk registers	The committee noted the RMOC guidance
NHSE national shared care protocols NHS England » Shared Care Protocols. These protocols have been developed as documents that can be adopted and adapted where relevant, using local governance processes for use. In most cases the need for changing the document should be minimal.	MGUG will use these templates as the starting point for any local shared care guidance that needs reviewed but will also work with the ICB medicines structures to adopt regional shared care guidance when this is available.

7) Appeals against earlier decisions by the APC

Product	Approved	Refused	Deferred	Notes
None				

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

- Guidance approved:
  - Hydroxychloroquine shared care guidance – the local guidance was approved. It is primarily based on the central RMOC document but recognises interim commissioning arrangements relating to ophthalmology screening capacity.
  - Erectile Dysfunction guideline - approved
  - Gender dysphoria – approved.
  - Antipsychotic leaflet - approved
- Guidance retired:
  - Branded prescribing.
- Guidance extended:
  - IMD guideline; request to extend to March 20235/9/22 agreed whilst regional work continues.

9) Miscellaneous decisions by the APC

Exenatide M/R	**GLP-1 shortages**. Colleagues from Gateshead trust asked for exenatide M/R to be temporarily added to the formulary to allow alternative options for patients who may be affected by the current supply issues with semaglutide and dulaglutide. The NENC diabetes clinical network endorsed this request and the following Primary Care diabetes society advice relating to the handling of this https://diabetesonthenet.com/wp-content/uploads/PCDS-GLP-1-RA-shortage-statement-1.pdf . Exenatide M/R, and the link to the PCDS advice, will be temporarily added to the formulary.

Potassium permanganate	At the July APC meeting it was decided to remove potassium permanganate from the formulary in response to a recent NPSA safety alert regarding inadvertent oral ingestion. Following feedback from primary care this decision is recognised as being too restrictive and potassium permanganate tablets for solution will be added back on to the formulary with a link to the NPSA safety alert along with a specific statement advising against issuing potassium permanganate on repeat prescription.
Testosterone for menopausal women	The committee agreed that testosterone for menopausal women should remain GREEN Plus and that issues around the guidance / monitoring should be referred to the MGUG. The formulary will reflect recent change in Testogel® strength.