

**North of Tyne, Gateshead and North Cumbria  
Area Prescribing Committee**

**Minutes of the meeting held on Tuesday 11<sup>th</sup> October 2022**

**Present**

Nicola Allen	Acting Operations Director & Clinical Lead for Community Services & OPMH Services	GHFT
David Campbell	Chief Pharmacist/Clinical Director for Medicines Optimisation (Chair)	NHCT
Ian Campbell	Assistant Director, Pharmacy and Medicines Optimisation	NUTH
Alasdair Green	Formulary Pharmacist	NHCT
Sue Dickinson	Director of Pharmacy	RDTC
Paul Fieldhouse	Clinical Director of Pharmacy	NCICFT
Matt Haggerty	Deputising for Tim Donaldson	CNTW
Naeem Iqbal	GP prescribing lead	NENC ICB 99C
Chris Jewitt	GP prescribing lead	NENC ICB 13T
Matthew Lowery	Formulary and Audit Pharmacist	NUTH
Helen Seymour	Senior Pharmacist	NECS
Sheetal Sundeep	Consultant Microbiologist	NHCT
Graham Syers	Clinical Director of Primary Care	NENC ICB 00L
Susan Turner	Pharmacist	NECS
Jane Welsh	Clinical Lead for Community Services	GHFT

**Apologies**

Tim Donaldson	Chief Pharmacist/Controlled Drugs Accountable Officer	CNTW
Matt Grove	Consultant Rheumatologist	NHCT
Alex Kent	Medical Director	NENC ICB 99C
Jane Lothian	Medical secretary Northumberland LMC	N LMC
Geraint Morris		NoT LPC
Mark Thomas	Chief Pharmacist	GHFT

**Member organisations**

GHFT	Gateshead Health NHS Foundation Trust
NENC ICB 13T	Newcastle Gateshead
NENC ICB 99C	North Tyneside
NENC ICB 01H	North Cumbria
NCICFT	North Cumbria Integrated Care Foundation Trust
NENC ICB 00L	Northumberland
NoT LPC	North of Tyne Local Pharmaceutical Committee
NNT LMC	Newcastle and North Tynesdie LMC
N LMC	Northumberland LMC
NHSE	NHS England
NHCT	Northumbria Healthcare NHS Foundation Trust
NECS	North of England Commissioning Support Organisation
CNTWT	Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
NUTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
RDTC	Regional Drugs and Therapeutics Centre
ST&G LPC	South Tyneside and Gateshead LPC

2022/48	<b>Declarations of interest</b> None
2022/49	<b>Appeals against previous decisions</b> None
2022/50	<b>Minutes and decision summary from previous meeting.</b> The following documents were accepted as a true record: <ul style="list-style-type: none"> <li>• Decision summary from 05/07/22.</li> <li>• Minutes from 05/07/22.</li> </ul>
2022/51	<b>Matters arising not on the agenda or Action Log.</b> At the July APC meeting it was decided to remove potassium permanganate tablets 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.
2022/52	<b>Action Log</b> The action log was reviewed and will be updated to reflect the following: <ul style="list-style-type: none"> <li>• 2019/53 Follitropin delta (Rekovel®) injection. The addition of Rekovel® to the formulary was approved in October 2019 for the purposes of a 100 patient evaluation only. By June 2021 only 40 patients had been treated and the deadline was extended to June 2022. The FSC has now recommended that the committee accepts lower numbers than the original 100 due to service suspension during COVID. Agreed. ML to chase.</li> <li>• 2021/39 Nasal Naloxone (Nyxoid®). M Haggerty is presenting a paper to CNTW medicines optimisation group in relation to nasal naloxone. There was a delay in starting to use this product but a subsequent national review of drug treatment confirmed its role. It is currently being made available in the area and no change to the formulary status is needed at this point. Update to come to January meeting</li> <li>• 2021/39 Ophthalmology products review. Action outstanding. ML informed the committee that work is now progressing well and that he is confident that a draft document will be presented at the January APC.</li> <li>• 2022/38 Hydroxychloroquine SCG. Agenda item; remove from action log.</li> <li>• 2022/41 ICS single formulary and NTAG terms of reference. Work continues under the remit of the ICB Medicines committee. Remove from APC action log.</li> </ul>

2022/53

### **Report from the Formulary Sub-committee**

The formulary website is available at [North of Tyne, Gateshead and North Cumbria Area Prescribing Committee Formulary](#).

### **Minutes and recommendations from the North of Tyne, Gateshead and North Cumbria FSC meeting held on 8/9/22:**

The above minutes and recommendations were received by the committee. The summary of recommendations made in relation to new product requests is listed in the decision summary.

The following specific points were highlighted for further consideration:

#### **Eloine® (20 mcg ethinylestradiol and 3 mg drospirenone)**

Approved by chair's action.

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 correspondence confirmed that the 20mcg version is particularly useful in PMS and PMDD as many of these women struggle with hormones in general and that 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.

#### **Eloine® (20 mcg ethinylestradiol and 3 mg drospirenone)**

Decision: Approved

#### **Estradot® patches**

Approved by chair's action.

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® patches they are likely to prefer these 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

#### **Estradot® patches**

Decision: Approved

#### **Nebulised colistimethate & nebulised gentamicin**

Nebulised colistimethate & nebulised gentamicin are both currently approved for use in bronchiectasis. The FSC considered an application for an extension to allow for use in patients on assisted ventilation, patients with tracheostomies and those with persistent bacterial bronchitis. The lower threshold (two

exacerbations) for starting inhaled therapy was discussed but it was recognised these patients would likely require a prolonged admission for IV antibiotics if they had a severe exacerbation. Primary care had raised concerns that the bronchiectasis patients on nebulised therapies didn't appear to be under regular specialist review and whether an AMBER status would be more appropriate for this cohort of patients. It was felt that the request was clinically appropriate but the formulary subcommittee recommended that the request was deferred subject to confirmation of current number of bronchiectasis patients and arrangements for follow up for these patients.

The applicant has subsequently confirmed:

- 1) The NEAVS home vent population are generally a distinct population from bronchiectasis with a <5% overlap
- 2) The NEAVS home vent patients are under regular follow due to clinical safety grounds as well as ventilator maintenance
- 3) The specialist team have a weekly MDT where they are systematically reviewing patient's antibiotic regimes and withdrawing in the absence of ongoing bacterial cultures. This would apply across the region for ventilated patients.

For the separate adult bronchiectasis population (formulary approval already in place) it was recognised that there are varying services across the region but the applicant confirmed that there are currently less than 20 patients at NUTH on nebulised gentamicin. As the trust supplies the nebuliser, and retains clinical oversight, the model of starting a nebulised antibiotic and then discharging to primary care for follow up was not recognised. Any patients lost to follow-up should be referred back to the specialist team.

Colomycin® use in bronchiectasis has not been as recently audited but internal estimates are that there are less than 50 patients on this therapy long term within our catchment. Subsequent primary care prescribing data has gone a long way to validating that assurance and therefore the committee approved the new application.

**Nebulised colistimethate & nebulised gentamicin for use in patients on assisted ventilation, patients with tracheostomies and those with persistent bacterial bronchitis.**

Decision: Approved

### **Metolazone**

A new licensed preparation of metolazone is now available under the brand name Xaqua®. The bioavailability of the new product is twice that of the originator product and therefore there is a risk of patient harm if patients are inadvertently switched without close monitoring. SPS have produced a briefing document and alerts have been put on primary care systems. The SPS briefing document has been shared with the North of Tyne, Gateshead and North Cumbria LPCs and local MO leads will advise practices further as deemed necessary.

**2022/54**

### **Report from the Medicines Guidelines and Use Group**

Draft minutes from meeting held on 5/9/22 were received and noted.

- Guidance/documents for approval:
  - NENC ICS recurrent UTI guidance and NENC ICS recurrent UTI summary flowchart. MGUG has fed back comments to the regional group who are reviewing the guidance and will then take through NTAG for regional approval. Removed from local work plan.
  - Hydroxychloroquine shared care guidance – the local guidance was

	<p>approved. It is primarily based on the central RMOc document but recognises interim commissioning arrangements relating to ophthalmology screening capacity.</p> <ul style="list-style-type: none"> <li>○ Erectile Dysfunction guideline - approved</li> <li>○ Urology guideline - a last minute concern about management of blocked catheters has been raised so this paper is currently back with MGUG until that is resolved. DC agreed to take chair's action if that is resolved to the satisfaction of MGUG.</li> <li>○ Gender dysphoria – approved. There have been some minor changes relating to differing assay levels from the labs across the region.</li> <li>○ Antipsychotic leaflet - approved</li> </ul> <ul style="list-style-type: none"> <li>● Guidance to retire: <ul style="list-style-type: none"> <li>○ Branded prescribing. There is national advice on the SPS website so local guidance is no longer needed.</li> </ul> </li> <li>● Guidance to extend: <ul style="list-style-type: none"> <li>○ IMD guideline; request to extend to March 2023 agreed whilst regional work continues.</li> </ul> </li> </ul>
<p><b>2022/55</b></p>	<p><b>Report from opiate/pain management sub-group</b></p> <ul style="list-style-type: none"> <li>• Notes from meeting on 7/7/22 were received and those from 6/10/22 will be shared as soon as they are finalised.</li> <li>• Quarter 1 data continues to show slow but encouraging progress and the wider engagement of the pain and MSK services as well as the AHSN network is helping raise awareness that this is not simply a prescribing issue.</li> </ul> <p>DC asked what other areas of practice would benefit from the success of this expanded and integrated focus on what is initially seen as a prescribing issue and it was agreed that antimicrobial stewardship is also a high priority for the area. Work has already commenced to try and expand engagement with other interested parties.</p> <p>There is also already work underway across the ICS to try and join up approaches to valproate prescribing and management of the associated risks.</p>
<p><b>2022/56</b></p>	<p><b>NENC ICS</b></p> <p>The following documents were all received and considered:</p> <ul style="list-style-type: none"> <li>● NENC Medicines Committee draft terms of reference</li> <li>● NENC MO Subcommittee (NTAG) Interim TOR</li> <li>● Minutes from formulary merging meeting</li> <li>● Paper from EM to ICB executive regarding decisions relating to the approval and funding of NICE TAs.</li> </ul> <p>The recently established ICB medicines committee is now the approval route for APC recommendations, up to a financial threshold of £250k, except for NICE TAs. The ICB executive has decided that NICE TAs will only be adopted once the relevant finances to allow in-year implementation have been identified. If system funding is not identified then the ICB exec will not approve the TA and accepts the risks associated with taking that position given that this is clearly at odds with the requirements of the NHS Constitution.</p> <p>NTAG is expected to have an expanded role in decision making around medicines, including maintenance of a single formulary, although the governance, workforce capacity and funding arrangements to support this infrastructure is not yet clear. Until that is clarified there appears to be a need</p>

	<p>for dual running of the new ICB structures and the existing APCs, with the latter feeding their current recommendations into the ICB structure. Concerns were raised about the ability to support additional work.</p> <p>Questions were asked about the future role of APCs. There is still no real clarity on their future functions although it has been recognised that local engagement is key to implementation of an ICS wide formulary and guidelines. Work has started on the merging of existing formularies but concerns were expressed that the scale of work involved has not been fully recognised and this has been started before there is full clarity on the underpinning governance structures.</p> <p>The current clinical leads from the former CCG areas (including prescribing leads who are members of this APC) are going through an HR consultation exercise at present and the potential loss of this expertise from the system is very concerning. It was acknowledged that it will take time for new structures, processes and personnel to evolve, and that the committee needs to remain engaged during this period. The potential loss of prescribing expertise and clinical engagement is concerning, particularly when it comes to implementation of wider medicines optimisation priorities. The chair agreed to share these concerns with officers of the ICB.</p>
<p><b>2022/57</b></p>	<p><b>Northern (NHS) Treatment Advisory Group (NTAG).</b>  <a href="http://ntag.nhs.uk/">http://ntag.nhs.uk/</a></p> <ul style="list-style-type: none"> <li>• Draft minutes from the meeting of 19/7/2022 were noted.</li> <li>• Approval of NEELI V 2022.2. The APC website will be updated to point directly to this updated guidance.</li> </ul>
<p><b>2022/58</b></p>	<p><b>RMOC</b></p> <p><b>Hydroxychloroquine and chloroquine retinopathy monitoring</b>  On behalf of the national Regional Medicines Optimisation Committees (RMOCs) system, RMOC (South) <a href="#">has developed practical recommendations for safe ophthalmology monitoring of patients who are receiving long term hydroxychloroquine or chloroquine</a>. The document outlines the risks of retinopathy and sets out a structured approach for health professionals to manage these risks.  It specifically states:  <i>4.7 In healthcare systems choosing to monitor patients at a level less than that proposed by the RCOphth, the rationale and agreement should be clearly documented, including the measures being taken to ensure patient safety, and consideration made as to increasing the level of monitoring over time. If the service is unable to implement the RCOphth guidance, inclusion in the commissioner and provider risk registers should be considered.</i>  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</p> <p><b>NHSE national shared care protocols</b>  The <a href="#">NHS England » Shared Care Protocols</a> 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. This shared care protocol includes all information required for safe prescribing in strict accordance with current guidance. Where the nationally published SCPs are adopted locally, organisations are</p>

	<p>responsible for taking them through their local medicines governance process before use, as for local SCP development and adoption. 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.</p> <p>Members had previously received an email inviting them to comment on the future role of RMOC. The committee awaits with interest the outcome of that national survey.</p>
<p><b>2022/59</b></p>	<p><b>NICE Technology Appraisals</b> The committee noted the recent decision by the NENC ICB executive to consider NICE TAs at the ICB medicines committee, or executive board depending on the financial implications, and will therefore no longer consider NICE TAs that would previously have been commissioned by CCGs. (ref 2022/56) The committee did decide, however, that until such times as NHSE specialised commissioning functions fall under the ICB and/or until we have a single formulary process, to continue to include medicines that are contained within NHSE specialised services circulars/commissioning commitments in our formulary.</p>
<p><b>2022/60</b></p>	<p><b>NHS England</b></p> <p>The following NHS England communications were noted and will be reflected in the formulary:</p> <ul style="list-style-type: none"> <li>• SSC2400: NICE Technology Appraisal Final Appraisal Determination: asciminib for treating chronic myeloid leukaemia after 2 or more tyrosine kinase inhibitors</li> <li>• SSC2401: Palivizumab passive immunisation against Respiratory Syncytial Virus (RSV) in at-risk infants (2022/23 Season)</li> <li>• SSC2402: NICE Technology Appraisal Final Appraisal Determination: nivolumab for adjuvant treatment of invasive urothelial cancer at high risk of recurrence</li> <li>• 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.</li> <li>• SSC2406: NICE Technology Appraisal Final Appraisal Determination: alpelisib with fulvestrant for treating hormone receptor-positive, HER2-negative, PIK3CA-mutated advanced breast cancer</li> <li>• SSC2407: NICE Technology Appraisal Final Appraisal Determination: nivolumab with ipilimumab for untreated unresectable malignant pleural mesothelioma</li> <li>• SSC2411: Specialised Commissioning update -NICE notification letter Jul-Oct</li> <li>• SSC2412: HST20 Selumetinib NICE notification letter and Appendix A</li> <li>• SSC2413: EAMS Voxelotor update letter to trusts</li> <li>• SSC2414: NICE Technology Appraisal Consultation Document: lenvatinib with pembrolizumab for untreated advanced renal cell carcinoma</li> <li>• SSC2415: NICE Technology Appraisal Final Appraisal Determination: atezolizumab for adjuvant treatment of resected non-small-cell lung cancer</li> <li>• SSC2418: Specialised Commissioning Update Sept 22</li> </ul>

	<ul style="list-style-type: none"> <li>• SSC2418: Table One</li> <li>• SSC2419: NHS England update on selected providers of Inherited White Matter Disorders Diagnostic and Management Service (IWMD) (All Ages)</li> <li>• SSC2420: NICE Technology Appraisal Final Appraisal Determination: oral azacitidine for maintenance treatment of acute myeloid leukaemia after induction therapy</li> <li>• SSC2423: NICE Technology Appraisal Final Appraisal Document: pembrolizumab for adjuvant treatment of renal cell carcinoma</li> <li>• SSC2424: NICE Technology Appraisal: TA821: Avalglucosidase alfa in Pompe disease</li> <li>• SSC2425: NICE Technology Appraisal TA804: Teduglutide for treating short bowel syndrome.</li> <li>• SSC2427: NICE Technology Appraisal Final Appraisal Document: palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy</li> <li>• SSC2428: NICE Technology Appraisal Final Appraisal Document: pembrolizumab for adjuvant treatment of resected stage 2B or 2C melanoma</li> </ul>
<b>2022/61</b>	<p><b>Chair's action</b></p> <ul style="list-style-type: none"> <li>• See 2022/53.</li> </ul>
<b>2022/62</b>	<p><b>Any other business</b></p> <p><b>GLP-1 shortages.</b></p> <p>Colleagues from Gateshead FT 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 committee agreed to this dependant on confirmation that the NENC diabetes clinical network endorsed this suggestion and were happy with the Primary Care diabetes society advice relating to the handling of this <a href="https://diabetesonthenet.com/wp-content/uploads/PCDS-GLP-1-RA-shortage-statement-1.pdf">https://diabetesonthenet.com/wp-content/uploads/PCDS-GLP-1-RA-shortage-statement-1.pdf</a>. That endorsement was received immediately following the meeting and therefore exenatide M/R, and the link to the PCDS advice, will be temporarily added to the formulary.</p> <p><b>Dressing formulary</b></p> <p>NA asked for confirmation that local wound formulary work should progress. The committee agreed that it should.</p>
	<p><b>Date and time of next meeting(s)</b></p> <p>Tuesday 10<sup>th</sup> January 2023 at 12.30 pm v TEAMS</p>



## 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 11<sup>th</sup> 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
<b>Methoxyflurane 99.9% inhalation vapour (Penthrox®) – Trauma related pain</b>	✓ <b>R</b>			<p>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.</p> <p><b>Decision:</b> Approved for trauma related pain in Emergency Departments, in adults only, as a RED drug.</p>
<b>Methoxyflurane 99.9% inhalation vapour (Penthrox®) – Procedural analgesia</b>	✓ <b>R</b>			<p>Requested instead of Entonox® for analgesia in procedures such as VAC dressing change/stent change/brachytherapy rod change.</p> <p><b>Decision: Approved</b> for procedural analgesia in adult patients, as a RED drug</p>
<b>Tedizolid (Sivextro®)</b>	✓ <b>R</b>			<p>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.</p> <p><b>Decision: Approved</b> for use on the advice of microbiologists / ID physicians, as a RED drug.</p>

<p><b>Estradiol valerate plus dienogest (Qlaira®)</b></p>	<p>✓ G+</p>		<p>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 2<sup>nd</sup> / 3<sup>rd</sup> line agent.</p> <p><b>Decision: Approved</b> as a GREEN Plus drug.</p>
<p><b>Eloine® (20 mcg ethinylestradiol and 3 mg drospirenone)</b></p>	<p>✓ G</p>		<p>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.</p> <p>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 correspondence 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.</p> <p><b>Decision: Approved</b></p>
<p><b>Estradot® patches</b></p>	<p>✓ G</p>		<p>Estradot patches are smaller, less irritating, more adherent and more cosmetically acceptable than alternatively available patches, whilst providing comparable serum oestradiol concentrations.</p> <p>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.</p> <p><b>Decision: Approved</b></p>

3) New formulations & extensions to use				
Product	Approved	Refused	Deferred	Notes
<b>Nebulised colistimethate &amp; nebulised gentamicin for use in patients on assisted ventilation, patients with tracheostomies and those with persistent bacterial bronchitis.</b>	✓ <b>G+</b>			Nebulised colistimethate & nebulised gentamicin are both 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.  <b>Decision: Approved</b>
<b>Hydrocortisone modified release capsules (Efmody®)</b>		✓		Requested for congenital adrenal hypoplasia. The EMA had stated that no claims on clinical superiority versus standard glucocorticoid therapy can be made for Efmody®. Efmody® 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.  <b>Decision: Refused.</b>
<b>Melatonin (Adaflex®) tablets</b>	✓ <b>A</b>			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®  <b>Decision: Approved</b> Adaflex® will be added to the formulary in place of Circadin® for children and young people in accordance with current formulary approvals for melatonin.
<b>Midazolam 5mg/ml (7.5ml) (Miprosed®)</b>	✓ <b>R</b>			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.  <b>Decision: Approved</b> for sedation and pre-medication in children, as a RED drug.
<b>Metformin (500mg oral powder sachets sugar free)</b>	✓ <b>G</b>			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.  <b>Decision: Approved</b>

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

<ul style="list-style-type: none"> <li>• SSC2400: NICE Technology Appraisal Final Appraisal Determination: asciminib for treating chronic myeloid leukaemia after 2 or more tyrosine kinase inhibitors</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2401: Palivizumab passive immunisation against Respiratory Syncytial Virus (RSV) in at-risk infants (2022/23 Season)</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2402: NICE Technology Appraisal Final Appraisal Determination: nivolumab for adjuvant treatment of invasive urothelial cancer at high risk of recurrence</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• 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.</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2406: NICE Technology Appraisal Final Appraisal Determination: apelisib with fulvestrant for treating hormone receptor-positive, HER2-negative, PIK3CA-mutated advanced breast cancer</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2407: NICE Technology Appraisal Final Appraisal Determination: nivolumab with ipilimumab for untreated unresectable malignant pleural mesothelioma</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2411: Specialised Commissioning update -NICE notification letter Jul-Oct</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2412: HST20 Selumetinib NICE notification letter and Appendix A</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2413: EAMS Voxelotor update letter to trusts</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2414: NICE Technology Appraisal Consultation Document: lenvatinib with pembrolizumab for untreated advanced renal cell carcinoma</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2415: NICE Technology Appraisal Final Appraisal Determination: atezolizumab for adjuvant treatment of resected non-small-cell lung cancer</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2418: Specialised Commissioning Update Sept 22 and Table</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2419: NHS England update on selected providers of Inherited White Matter Disorders Diagnostic and Management Service (IWMD) (All Ages)</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2420: NICE Technology Appraisal Final Appraisal Determination: oral azacitidine for maintenance treatment of acute myeloid leukaemia after induction therapy</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2423: NICE Technology Appraisal Final Appraisal Document: pembrolizumab for adjuvant treatment of renal cell carcinoma</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2424: NICE Technology Appraisal: TA821: Avalglucosidase alfa in Pompe disease</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2425: NICE Technology Appraisal TA804: Teduglutide for treating short bowel syndrome.</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2427: NICE Technology Appraisal Final Appraisal Document: palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy</li> </ul>	The formulary will reflect the SSC position
<ul style="list-style-type: none"> <li>• SSC2428: NICE Technology Appraisal Final Appraisal Document: pembrolizumab for adjuvant treatment of resected stage 2B or 2C melanoma</li> </ul>	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)				
<p><i>Hydroxychloroquine and chloroquine retinopathy monitoring</i></p> <p>On behalf of the national Regional Medicines Optimisation Committees (RMOCs) system, RMOC (South) <a href="#">has developed practical recommendations for safe ophthalmology monitoring of patients who are receiving long term hydroxychloroquine or chloroquine</a>. The document outlines the risks of retinopathy and sets out a structured approach for health professionals to manage these risks.</p> <p>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</p> <p><b>NHSE national shared care protocols <a href="#">NHS England » Shared Care Protocols</a>.</b></p> <p>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.</p>		<p>The committee noted the RMOC guidance</p> <p>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.</p>		
7) Appeals against earlier decisions by the APC				
Product	Approved	Refused	Deferred	Notes
None				
8) Guidelines. <a href="http://www.northoftyneapc.nhs.uk/guidance/">http://www.northoftyneapc.nhs.uk/guidance/</a>				
<ul style="list-style-type: none"> <li>• Guidance approved: <ul style="list-style-type: none"> <li>○ 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.</li> <li>○ Erectile Dysfunction guideline - approved</li> <li>○ Gender dysphoria – approved.</li> <li>○ Antipsychotic leaflet - approved</li> </ul> </li> <li>• Guidance retired: <ul style="list-style-type: none"> <li>○ Branded prescribing.</li> </ul> </li> <li>• Guidance extended: <ul style="list-style-type: none"> <li>○ IMD guideline; request to extend to March 2023/5/9/22 agreed whilst regional work continues.</li> </ul> </li> </ul>				
9) Miscellaneous decisions by the APC				
Exenatide M/R	<p><b>GLP-1 shortages.</b></p> <p>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.</p> <p>The NENC diabetes clinical network endorsed this request and the following Primary Care diabetes society advice relating to the handling of this <a href="https://diabetesonthenet.com/wp-content/uploads/PCDS-GLP-1-RA-shortage-statement-1.pdf">https://diabetesonthenet.com/wp-content/uploads/PCDS-GLP-1-RA-shortage-statement-1.pdf</a> .</p> <p>Exenatide M/R, and the link to the PCDS advice, will be temporarily added to the formulary.</p>			

<b>Potassium permanganate</b>	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.
<b>Testosterone for menopausal women</b>	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.