

## County Durham & Tees Valley Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Thursday 13<sup>th</sup> May 2021**

### Classification of products:

- G** **Green drug** - Can be initiated and prescribed in all care settings **○** - Second line / alternative green drug
- A** **Amber Specialist initiation / recommendation drug**. Can be recommended by a specialist for initiation in primary care; or be initiated by a specialist and transferred to primary care once the patient stabilised. In some cases there may be a further restriction for use outlined - these will be defined in each case.
- ASC** **Amber Shared Care drug** - These are specialist drugs which must be initiated by the specialist, but with the potential to transfer to primary care within written and agreed shared care protocols and according to the agreed process for transfer of care
- R** **Red drug** - Drugs that should remain under the total responsibility of the specialist. Usually considered as "hospital only" drugs
- X** **Not Approved** - Drugs that have been considered by the APC or other approved body and are not approved for prescribing within County Durham & Tees Valley.
- ⊘** **Not Reviewed** - Drugs that haven't been reviewed by the APC yet. This usually means that no application has been received or that an application is in progress. These drugs are not normally considered appropriate for prescribing in County Durham & Tees Valley.
- **Unclassed Drug** - Drugs that do not fall into one of the above categories

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
<b>1) Requests deferred from previous meetings</b>				
None				
<b>2) New Requests</b>				
<b>Buprenorphine oral lyophilisate (Espranor®)</b>		✓		<p>Previously rejected in March 2020 by APC following a submission from Spectrum CIC for use in the community following release from prison.</p> <p>New request from We Are With You - commissioned to provide specialist community drug and alcohol services in Redcar and Cleveland and Darlington.</p> <p><b>Decision:</b> Not approved. The FSG and APC came to this recommendation not to approve addition to the formulary because:</p> <ul style="list-style-type: none"> <li>Concerns were expressed around patient safety implications including potential variation in bioavailability, confusion arising from multiple dosage forms of buprenorphine and the impact on community pharmacy supervised services – this was expressed previously by North of Tyne and in March 2020 by APC.</li> <li>Risk of dispensing errors in community pharmacies from having Espranor and SL forms both available when 2mg and 8mg strengths both available – people may not realise the products and dose are different.</li> <li>No evidence presented that not having this on formulary precludes patients from having a treatment choice which could give them a better experience and outcomes compared to SL buprenorphine (evidence?)</li> <li>Application does not have the support of local authorities in County Durham &amp; Tees Valley who are commissioners of Drug Misuse Services.</li> </ul>

DECISION SUMMARY

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<b>3) New formulations &amp; extensions to use</b>				
None				
<b>4) Products considered by NICE</b>				
TA671: Mepolizumab for treating severe eosinophilic asthma	✓ <b>R</b>			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA672: Brolucizumab for treating wet age-related macular degeneration	✓ <b>R</b>			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA673: Niraparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy	✓ <b>R</b>			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA674: Pembrolizumab for untreated PD-L1-positive, locally advanced or metastatic urothelial cancer when cisplatin is unsuitable (terminated appraisal)				The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA675: Vernakalant for the rapid conversion of recent onset atrial fibrillation to sinus rhythm (terminated appraisal)				The formulary will reflect the TAG – CCG is the responsible commissioner.
TA676: Filgotinib for treating moderate to severe rheumatoid arthritis	✓ <b>R</b>			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA677: Autologous anti-CD19-transduced CD3+ cells for treating relapsed or refractory mantle cell lymphoma	✓ <b>R</b>			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA678: Omalizumab for treating chronic rhinosinusitis with nasal polyps (terminated appraisal)	✓ <b>X</b>			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA679: Dapagliflozin for treating chronic heart failure with reduced ejection fraction	✓ <b>A</b>			The formulary will reflect the TAG – CCG is the responsible commissioner. Noted STHFT Cardiology have developed local information to support use.
HST14: Metreleptin for treating lipodystrophy	✓ <b>R</b>			The formulary will reflect the TAG – NHS England is the responsible commissioner.

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<b>TA680: Lenalidomide maintenance treatment after an autologous stem cell transplant for newly diagnosed multiple myeloma</b>	✓ <b>R</b>			The formulary will reflect the TAG – NHS England is the responsible commissioner.
<b>TA681: Baricitinib for treating moderate to severe atopic dermatitis</b>	✓ <b>R</b>			The formulary will reflect the TAG – CCG is the responsible commissioner.
<b>TA682: Erenumab for preventing migraine</b>	✓ <b>R</b>			The formulary will reflect the TAG – CCG is the responsible commissioner.
<b>TA683: Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic, non-squamous non-small-cell lung cancer</b>	✓ <b>R</b>			The formulary will reflect the TAG – NHS England is the responsible commissioner.
<b>TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease</b>	✓ <b>R</b>			The formulary will reflect the TAG – NHS England is the responsible commissioner.
<b>TA685: Anakinra for treating Still's disease</b>	✓ <b>R</b>			The formulary will reflect the TAG – NHS England is the responsible commissioner.
<b>TA686: Blinatumomab for previously treated Philadelphia-chromosome-positive acute lymphoblastic leukaemia (terminated appraisal)</b>				The formulary will reflect the TAG – NHS England is the responsible commissioner.
<b>TA687: Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy</b>	✓ <b>R</b>			The formulary will reflect the TAG – NHS England is the responsible commissioner.
<b>TA688: Selective internal radiation therapies for treating hepatocellular carcinoma</b>	✓ <b>R</b>			The formulary will reflect the TAG – NHS England is the responsible commissioner.
<b>5) Appeals against earlier decisions by the APC</b>				
None				
<b>6) Products considered by NTAG</b>				
<b>Flash Glucose Monitoring – updated</b>	✓ <b>A</b>			CCG commissioned The formulary will reflect the NTAG recommendation. (noted NY CCG do not commission for use in pregnancy and Type 2 diabetes and STHFT aware of this for North Yorkshire patients).

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<b>Teriparatide for atypical fractures – reviewed &amp; no changes</b>	✓ ✗			CCG commissioned tariff excluded drug. The formulary will reflect the NTAG recommendation.
<b>Xoneva® for nausea &amp; vomiting in pregnancy – reviewed &amp; no changes</b>	✓ ✗			CCG commissioned tariff included drug. The formulary will reflect the NTAG recommendation.
<b>7) Miscellaneous decisions by the APC</b>				
<b>Monthly oral ibandronic acid 150mg film coated tablets</b>	✓ G			CCG commissioned tariff included drug. To review the current formulary position for monthly oral ibandronic acid as currently listed as non-formulary but should be on the formulary as per NICE TA464 alongside all the other oral bisphosphates for osteoporosis. <b>Decision:</b> Change from NOT APPROVED to Green drug as an option as per NICE TA464.
<b>Prucalopride for chronic constipation in men</b>	✓ A			CCG commissioned tariff included drug. Prucalopride (Resolor®) has been indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief i.e. in men as well as women since the product license was updated in May 2015. <b>Decision:</b> Add to formulary as AMBER SI for use men as well as women in whom at least two laxatives from different classes, at the highest tolerated recommended doses for at least 6 months has failed to provide adequate relief and invasive treatment for constipation is being considered.
<b>Calmurid - remove from formulary as discontinued</b>	✓			CCG commissioned tariff included drug. <b>Decision:</b> Agreed to remove from formulary as discontinued
<b>Adalimumab</b>	✓ ✗			NHSE commissioned tariff excluded drug <b>Decision:</b> Add to formulary as NOT APPROVED for this indication as per the NHSE policy - Clinical Commissioning Policy Statement Use of adalimumab for refractory chronic non-bacterial osteomyelitis osteitis (CNO) (all ages).
<b>Spirolactone RAG review</b>	✓			CCG commissioned tariff included drug. Review of the RAG status of Spirolactone on the formulary (primarily for its hypertension indication) following a query at March 2021 APC when drug monitoring guidelines approved. It is currently listed on the formulary as Green+ drug (Notes: post-acute myocardial infarction patients and patients with heart failure treatment should be initiated on instructions from a cardiologist or GP with a specialist interest in cardiology. Spirolactone is first choice (ahead of eplerenone) for severe heart failure.) <b>Decision:</b> It was agreed to class as AMBER SI for heart failure or ascites and GREEN for hypertension. This is in line with other local formularies and relevant NICE Clinical Guidelines.

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<b>Clonidine 25mcg tablets for sedation</b>	✓ <b>R</b>			CCG commissioned tariff included drug. <b>Decision:</b> Add to formulary as a RED drug for use in intensive care only.
<b>Cyproheptadine 4mg tablets for Serotonin syndrome</b>	✓ <b>R</b>			CCG commissioned tariff included drug. <b>Decision:</b> Add to formulary as a RED drug for use in emergency management of serotonin syndrome in hospital only. Note on the list of Royal College of Medicine recommended antidotes to be available within a hospital within one hour.
<b>Cimetidine, Famotidine and Nizatidine (oral forms)</b>	✓ <b>G</b>			CCG commissioned tariff included drug. <b>Decision:</b> Add to formulary as Green drugs due to ongoing long-term supply issues with ranitidine.
<b>Droperidol 2.5mg/ml injection</b>	✓ <b>R</b>			CCG commissioned tariff included drug. <b>Decision:</b> Add to formulary as a Red drug for post-surgery nausea & vomiting following a request from CDDFT
<b>Sodium Glycerophosphate 21.6% injection</b>	✓ <b>R</b>			CCG commissioned tariff included drug. <b>Decision:</b> Add to formulary as a Red drug as an alternative to phosphate polyfusor following a request from CDDFT.
<b>Nebulised Gentamicin injection</b>	✓ <b>A</b>			CCG commissioned tariff included drug. <b>Decision:</b> it was agreed to change from red (specialist only) to amber SI (specialist initiation) for long term therapy in non-cystic fibrosis bronchiectasis usually in patients having > 3 exacerbations per annum with an organism identified as being sensitive to gentamicin. This is the same as the NoT formulary position. This also mirrors how the drug is currently prescribed in practice by CDDFT, STHFT and NTHFT. To specific brand required on prescription as need to use alcohol free formulation. The following brands of gentamicin are suitable for nebulisation as neither product contain alcohol (which can cause bronchospasm): <ul style="list-style-type: none"> <li>• Cidomycin®</li> <li>• Genticin® Injectable (Amdipharm UK Limited)</li> </ul>

The following guidelines were presented to and approved at the May 2021 meeting of the APC:

- TEWV PHARM-0043-v5.1 Citalopram Escitalopram - dose reduction ECG algorithm
- CD&T APC Guidance for Hypogonadism Management in Primary Care

The following shared care guidelines were presented to and approved at the May 2021 meeting of the APC:

- Nil

Other documents presented to and approved at the May 2021 meeting of the APC:

- RMOC Shared Care for Medicines Guidance: A Standard Approach.
- CD&T APC Template for Shared Care Guidelines – updated to reflect RMOC template.