

County Durham & Tees Valley Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Thursday 12th November 2020**

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 & Darlington.
- ⊘** **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 & Darlington.
- **Unclassed Drug** - Drugs that do not fall into one of the above categories

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
1) Requests deferred from previous meetings				
None				
2) New Requests				
Melatonin modified release, Slenyto®, 1mg, 5mg tablets for the treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient.	 ASC			<p>CCG commissioned tariff included drug.</p> <p>Slenyto® is currently the only melatonin product licensed for use in children and adolescents. May reduce prescribing of the more costly unlicensed Melatonin liquid preparations in this patient population.</p> <p>Proposal is to approve Slenyto® melatonin 1mg and 5mg modified release tablets in line with licensed indications only (i.e Autism Spectrum Disorder and or Smith-Magenis syndrome) once guidance from TEVV in place and supported by Acute Trust Paediatricians.</p> <p>1st line remains: melatonin 2mg modified release tablets (Circadin®), crushing if needed</p> <p>Rosemont melatonin 5mg/5ml oral solution (alcohol-free and propylene glycol free) - for patients only unable to use crushed tablets.</p> <p>Decision: approved for licensed indication in children with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome only, as licensed product in this patient group.</p> <p>(note due potential financial implications this requires clarification if final approval required from CCG Exec Committees)</p>

DECISION SUMMARY

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5 mg of fluorouracil and 100 mg of salicylic acid (SPC) (0.5% 5-FU and 10% salicylic acid) Actikerall® Cutaneous Solution	✓ G			Requested as an additional option for management of actinic keratosis. Current formulary = Efudix, Solaraze, and Aldara – all listed as AMBER SI Use supported and included in Primary Care Dermatology Society Actinic Keratosis guideline. Preferred to Efudix in severe lesions. Decision: approved as GREEN drug, plus changing Efudix, Solaraze, and Aldara to GREEN drugs.
3) New formulations & extensions to use				
None				
4) Products considered by NICE				
TA640: Treosulfan with fludarabine for malignant disease before allogeneic stem cell transplant	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA641: Brentuximab vedotin in combination for untreated systemic anaplastic large cell lymphoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA642: Gilteritinib for treating relapsed or refractory acute myeloid leukaemia	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA643: Entrectinib for treating ROS1-positive advanced non-small-cell lung cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA644: Entrectinib for treating NTRK fusion-positive solid tumours	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA645: Avelumab with axitinib for untreated advanced renal cell carcinoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA646: Glasdegib with chemotherapy for untreated acute myeloid leukaemia (terminated appraisal)				The formulary will reflect the TAG – NHS England is the responsible commissioner (NICE unable to make a recommendation).
TA647: Eculizumab for treating relapsing neuromyelitis optica (terminated appraisal)				The formulary will reflect the TAG – NHS England is the responsible commissioner (NICE unable to make a recommendation).
TA648: Dupilumab for treating chronic rhinosinusitis with nasal polyps (terminated appraisal)	✓ X			The formulary will reflect the TAG – CCG is the responsible commissioner (NICE unable to make a recommendation). Add to the formulary as NOT APPROVED for this indication as the company has confirmed that it does not intend to make a submission for the appraisal because there is unlikely to be sufficient evidence that the technology is a cost-effective use of NHS resources in this population.)

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TA649: Polatuzumab vedotin with rituximab and bendamustine for treating relapsed or refractory diffuse large B-cell lymphoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA650: Pembrolizumab with axitinib for untreated advanced renal cell carcinoma	✓ X			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA651: Naldemedine for treating opioid-induced constipation	✓ A			The formulary will reflect the TAG – CCG is the responsible commissioner.
5) Appeals against earlier decisions by the APC				
None				
6) Products considered by NTAG				
Brolucizumab for wAMD		✓		CCG commissioned tariff excluded drug. The formulary will reflect the NTAG recommendation.
Semaglutide (oral) for type 2 diabetes	✓ G			CCG commissioned tariff included drug. The formulary will reflect the NTAG recommendation.
7) Miscellaneous decisions by the APC				
Diltiazem 2% rectal ointment	✓ A			CCG commissioned tariff included drug. Decision: Add to formulary as AMBER SI as an additional option to the cream with sentence to use the most effective product.
Hydrocortisone Colifoam® Foam enema	✓			CCG commissioned tariff included drug. Supply problem since June 2018 - now discontinued (July 2020) Decision: Delete from formulary
Acetic acid 5% solution	✓ R			CCG commissioned tariff included drug. Acetic acid 3% (Unlicensed) is on formulary but now the standard CDDFT now get is 5%. Decision: Add to formulary as RED drug
Flecainide 150mg in 15mL injection	✓ R			CCG commissioned tariff included drug. Is now unlicensed and needs separate entry for injection. Decision: Add to formulary as RED drug.
Isoprenaline injection 200microgram per	✓ R			CCG commissioned tariff included drug. The 2mg in 2ml isoprenaline injection has a long term shortage Decision: Add to formulary as RED drug as an alternative strength.
Morphine 100microg per ml oral solution	✓ R			CCG commissioned tariff included drug. Decision: Add to formulary as RED drug for use in babies.

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Sucralfate 1g/5ml oral suspension	<p>✓ A bile reflux and stomal ulceration</p> <p>R Short term use post RFA for Barret's Oesophagus and Endoscopic Mucosal Resection (EMR)</p>			<p>CCG commissioned tariff included drug.</p> <p>Sucralfate suspension was previously removed from formulary due to issues with supply of the unlicensed product. Licensed version is now available.</p> <p>Decision: Add to formulary as per North of Tyne formulary position.</p>
Topiramate	<p>✓ G migraine prophylaxis</p>			<p>CCG commissioned tariff included drug.</p> <p>When did the formulary harmonisation it wasn't included on the CDD or TMGG formulary at that point, it was already on STEes formulary but without RAG status. The decision of the group was to add it to the new formulary as amber SI. However subsequently missed off the formulary.</p> <p>Decision: Add to formulary as GREEN drug for migraine prophylaxis with alert around need for adequate contraception if appropriate.</p> <p>No change to AMBER SI status for epilepsy.</p>
Denosumab – review of RAG status for osteoporosis	<p>✓ A</p>			<p>CCG commissioned tariff included drug.</p> <p>Decision: Change to AMBER Specialist Initiation drug from AMBER shared care with updated osteoporosis guideline in place to support this change.</p>
Lift Glucose shot 60ml – add to formulary for mild hypoglycaemia in Type 1 diabetes	<p>✓ A</p>			<p>CCG commissioned tariff included drug.</p> <p>Decision: Add to formulary as AMBER Specialist Recommendation for use only in children or vulnerable patients when unable to buy this or similar products over the counter as per guidance to exceptions to OTC guidance i.e.</p> <ul style="list-style-type: none"> • Circumstances where the prescriber believes that in their clinical judgement, exceptional circumstances exist that warrant deviation from the recommendation to self-care. • Individual patients where the clinician considers that their ability to self-manage is compromised as a consequence of medical, mental health or significant social vulnerability to the extent that their health and/or wellbeing could be adversely affected, if reliant on self-care. To note that being exempt from paying a prescription charge does not automatically warrant an exception to the guidance. Consideration should also be given to safeguarding issues.

DECISION SUMMARY

The following guidelines were presented to and approved at the November 2020 meeting of the APC:

- CD&T APC Transanal Irrigation Guidelines – reviewed & updated.
- CD&T APC Vitamin D Guideline – reviewed and updated.
- Tapentadol Dose Reduction Guidance for Primary Care.
- Northern England Evaluation and Lipid Intensification guideline.
- TEWV GP Information Sheet on Clozapine – reviewed and updated

The following shared care guidelines were presented to and approved at the September 2020 meeting of the APC:

- Sativex® Shared Care Guideline from Sunderland and Newcastle for patients in APC patch under their care.

Other documents presented to and approved at the November 2020 meeting of the APC:

- Nil.