

County Durham & Tees Valley Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Thursday 10th March 2022**

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	
1) Requests deferred from previous meetings				
None				
2) New Requests				
Tirbanibulin (Klisyri®) 10 mg/g ointment for actinic keratosis	✓ G			<p>CCG Commissioned, tariff included drug.</p> <p>Indicated for the field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis (Olsen grade 1) of the face or scalp in adults. Requested as an addition to:</p> <ul style="list-style-type: none"> Actikerall 5mg/g + 100g cutaneous solution Solaraze 3% gel (3% diclofenac sodium sodium hyaluronate 2.5%) Efudix (5% w/w furouracil) Aldara (Imiquimod 5% cream) <p>The short and simple treatment course of tirbanibulin (5 days) may be considered an advantage compared to other options with longer treatment durations. The mild to moderate side effect profile of tirbanibulin and efficacy profile will lead clinicians to consider tirbanibulin as a treatment option instead of other potent treatments, which are often associated with a higher frequency and severity of local skin reactions.</p> <p>Note: No clinical data on treatment for more than 1 treatment course of 5 consecutive days are available. If recurrence occurs, or new lesions develop within the treatment area, other treatment options should be considered.</p> <p>Decision: approved as a GREEN drug as an additional option. To be used as per Primary Care Dermatology Society Guidelines for actinic keratosis when these are updated to include Tirbanibulin.</p>

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3) New formulations & extensions to use				
None				
4) Products considered by NICE				
TA748: Mexiletine for treating the symptoms of myotonia in non-dystrophic myotonic disorders	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA749: Liraglutide for managing obesity in people aged 12 to 17 years (terminated appraisal)	✓ X			The formulary will reflect the TAG – NHS England is the responsible commissioner. (NICE unable to make a recommendation).
TA750: Olaparib for maintenance treatment of BRCA mutation-positive metastatic pancreatic cancer after platinum-based chemotherapy (terminated appraisal)	✓ X			The formulary will reflect the TAG – NHS England is the responsible commissioner. (NICE unable to make a recommendation).
TA751: Dupilumab for treating severe asthma with type 2 inflammation	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA752: Belimumab for treating active autoantibody-positive systemic lupus erythematosus	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA753: Cenobamate for treating focal onset seizures in epilepsy	✓ A			The formulary will reflect the TAG – CCG is the responsible commissioner. Add to formulary as a SPECIALIST INITIATION drug for this indication.
TA754: Mogamulizumab for previously treated mycosis fungoides and Sézary syndrome	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA755: Risdiplam for treating spinal muscular atrophy	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA756: Fedratinib for treating disease-related splenomegaly or symptoms in myelofibrosis	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA757: Cabotegravir with rilpivirine for treating HIV-1	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA758: Solriamfetol for treating excessive daytime sleepiness caused by narcolepsy	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner

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TA759: Fostamatinib for treating refractory chronic immune thrombocytopenia	✓ ✗			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA760: Selpercatinib for previously treated RET fusion-positive advanced non-small-cell lung cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA761: Osimertinib for adjuvant treatment of EGFR mutation-positive non-small-cell lung cancer after complete tumour resection	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (updated)	✓			The formulary will reflect the TAG – CCG is the responsible commissioner Decision: update RAG status to SPECIALIST INITIATION from RED for persistent hyperkalaemia. To remain RED for emergency acute treatment.
5) Appeals against earlier decisions by the APC				
None				
6) Products considered by NTAG				
None				
7) Miscellaneous decisions by the APC				
Ursodeoxycholic acid 250mg capsules	✓ G			CCG Commissioned, tariff included drug. Currently Ursodeoxycholic Acid capsules are not on the CDTV formulary, only tablets. Checked the drug tariff and although only the 250mg strength available in capsule form, they are cheaper than the tablets. Noted that product license between tablets and capsules may differ and this should be borne in mind when prescribing. Decision: to add Ursodeoxycholic Acid capsules in addition to the tablets as GREEN drugs
Duoresp Spiromax 160/4.5 inhaler	✓ G			CCG Commissioned, tariff included drug. Duoresp Spiromax has had a license change and now is licensed in asthma in patients over 12yrs in a fixed dose regime for the 160/4.5 and 320/9 doses. They also have an >12yrs MART license for the 160/4.5 dose. Respiratory CAG proposes that the 160/4.5 dose both in fixed and MART regime would be a valuable addition to the paediatric asthma guideline. Decision: to add to formulary and paediatric asthma guidelines as a GREEN drug.

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Sucralfate tablets	✓			CCG Commissioned, tariff included drug. Request to consider adding tablet preparation to the formulary entry for sucralfate (only oral solution currently listed on CD&T formulary) Decision: Do not add to formulary as appears only licensed product is oral solution. Tablets not listed in drug tariff and no SPC available.
Esomeprazole 40mg tablets	✓ A			CCG Commissioned, tariff included drug. Request to change from Green+ to Black drug. Decision: to keep as AMBER Specialist Initiation in CD&T due to levels of prescribing.
Qlaira contraceptive pill	✓			CCG Commissioned, tariff included drug. Request to add to formulary as BLACK drug from NY CGG (not currently listed on CD&T formulary). Decision: to remain non-formulary in CD&T as no formulary application ever received plus very low levels of prescribing.
Zonisamide –add 100mg/5ml oral suspension (licensed)	✓			CCG Commissioned, tariff included drug. Decision: agreed to add note to CD&T the formulary entry: Prescribing zonisamide 100mg/5ml oral suspension (licensed) instead of zonisamide 50mg/5ml oral suspension (unlicensed) is best practice (CAUTION: change in strength).
Loperamide	✓			CCG Commissioned, tariff included drug. May reduce inappropriate use of loperamide orthodispersible tablets which are currently non-formulary. Decision: To add the following note to formulary that oro-dispersible tablets should not be routinely used. They are approved for • short term use in patients who cannot tolerate plain tablets or capsules • patients undergoing chemo therapy where capsules or plain tablets have been ineffective • Patients with dysphagia e.g. upper GI cancer patients Patients with high output stomas should, wherever possible, use either capsules or plain tablets. If needed, capsules can be opened and the contents mixed with a small amount of water, jam or yoghurt. Alternatively, the plain tablets can be crushed and mixed with water or soft food (off label). This is a useful option if individuals are seeing undigested capsules or tablets in their stool or stoma collection bag.
Acenocoumarol	✓ G			Decision: Changed to a GREEN drug.
Rivaroxaban for CAD/PAD	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Sodium chloride 7% nebs	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Vitamin E suspension	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Sucralfate oral suspension	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.

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Esomeprazole	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Omeprazole suspension	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Balsalazide	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Sulfasalazine (gastro indications)	✓ ASC			Decision: Changed to an AMBER SHARED CARE drug.
Budesonide (Enterocort®)	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Leicarbon A Suppositories	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Naldemidine for OIC	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Pancrex V Capsules	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Colesevelam	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Flutter device	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Melatonin (neurology)	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Chlordiazepoxide	✓ R			Decision: Changed to a RED drug.
2nd gen antipsychotics – oral	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Carbamazepine for mania	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Lamotrigine for mania	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Valproic acid in men	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Sodium valproate for bipolar in men	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Duloxetine for depression/diabetic neuropathy	✓ G			Decision: Changed to a GREEN drug.
Reboxetine	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Fentanyl (Abstral®) for palliative care	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Methadone (pain in palliative care)	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Tapentadol	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Lidocaine patches	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Brivacetam	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.

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Carbamazepine (epilepsy)	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Clobazam	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Clonazepam	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Eslicarbazepine	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Ethosuximide	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Gabapentin	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Lacosamide	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Lamotrigine	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Levetiracetam	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Oxcarbazepine	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Perampanel	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Phenobarbital	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Phenytoin	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Pregabalin	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Piracetam	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Primidone	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Sodium valproate in men (epilepsy)	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Tiagabine	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Topiramate	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Vigabatrin	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Zonisamide	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Co-beneldopa	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Co-careldopa	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Stavelo®, Stravasi®	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Pramipexole	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.

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Ropinirole	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Rotigotine	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Selegiline	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Rasagiline	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Entacapone	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Opicapone	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Safinamide	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Orphenadrine	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Procyclidine	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Trihexylphenidyl	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Tetrabenazine	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Haloperidol for tics	✓ G			Decision: Changed to a GREEN drug.
TB drugs	✓ A			Decision: Changed to RED drugs.
Insulin degludec	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Toujeo® insulin	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Metformin for Polycystic Ovary Syndrome	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Linagliptin	✓ G			Decision: Changed to a GREEN drug.
Hydrocortisone granules (Alkindi®)	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Bromocriptine	✓ A			Decision: To clarify on formulary that AMBER Specialist Initiation (AMBER Specialist Recommendation when used to suppress lactation).
Cabergoline	✓ A			Decision: To clarify on formulary that AMBER Specialist Initiation (AMBER Specialist Recommendation when used to suppress lactation).
LHRH analogues	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Megestrol	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Norethisterone (chapter 8)	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Medroxyprogesterone (chapter 8)	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.

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Anastrozole	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Exemestane	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Letrozole	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Tamoxifen	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Raloxifene	✓ A			Decision: To clarify on formulary that is AMBER Specialist Recommendation for osteoporosis and AMBER Specialist Initiation for breast cancer.
Bicalutamide	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Flutamide	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Cyproterone	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Degarelix	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
St Mark's Solution	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Sodium clodronate (oncology pts)	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Sevelamer (non-dialysis)	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Lanthanum (non-dialysis)	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Patiromer	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Hylo-Forte eye drops	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Tacrolimus Ointment	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Pimecrolimus Ointment	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Glycopyrrolate 1% cream	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Glycopyrronium oral solution (Sialanar®)	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.
Bisacodyl rectal solution	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Alprostadil for erectile dysfunction	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Invicorp injection for erectile dysfunction	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Initiation drug.
Diltiazem rectal ointment/cream	✓ A			Decision: To clarify on formulary that is an AMBER Specialist Recommendation drug.

The following guidelines were presented to and approved at the March 2022 meeting of the APC:

- County Durham Erectile Dysfunction Guidelines – updated
- CD&T Cow's Milk Intolerance Guidelines

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- TEWV Anxiety Guidelines - updated
- TEWV Safe transfer of prescribing guidance - updated
- National Guidance for Lipid Management for Primary and Secondary Prevention of CVD – updated to include inclisiran and bempedoic acid

The following shared care guidelines were presented to and approved at the March 2022 meeting of the APC:

- Cinacalcet SCG – reviewed
- TEWV Risperidone LAI SCG
- TEWV Guanfacine SCG – updates around pregnancy

Other documents presented to and approved at the March 2022 meeting of the APC:

- TEWV Medicines Optimisation - Interactive Guide for External Stakeholders
- NHS England and Changing Health Low Calorie Diets pilot

The APC agreed to recommend extending the review date of the following guideline by a further 12 months as no changes required:

- CD&TV CCGs Position Statement on Nefopam.
- Guidelines for Self Monitoring of Blood Glucose (only recently been implemented due to COVID-19)