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 September 2020**

Classification of products:

G **Green drug** - Can be initiated and prescribed in all care settings O- 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

✕ **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.			✓	CCG commissioned tariff included drug. 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. 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 TEWV in place and supported by Acute Trust Paediatricians. 1st line remains: melatonin 2mg modified release tablets (Circadin®), crushing if needed Rosemont melatonin 5mg/5ml oral solution (alcohol-free and propylene glycol free) - for patients only unable to use crushed tablets. Existing patients with ASD and and / or Smith-Magenis requiring melatonin should not be switched to Slenyto®. This would be for new patients only with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome. **Decision:** decision deferred to gather extra information on formulary position in other APCs across the north of England.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
3) New formulations & extensions to use				
None				
4) Products considered by NICE				
TA626: Avatrombopag for treating thrombocytopenia in people with chronic liver disease needing a planned invasive procedure	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA631: Fremanezumab for preventing migraine	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner. (note due financial implications this requires final approval from CCGs)
TA632: Trastuzumab emtansine for adjuvant treatment of HER2-positive early breast cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA633: Ustekinumab for treating moderately to severely active ulcerative colitis	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA634: Daratumumab with lenalidomide and dexamethasone for untreated multiple myeloma (terminated appraisal)		✓		The formulary will reflect the TAG – NHS England is the responsible commissioner (NICE unable to make a recommendation).
TA635: Ramucirumab with erlotinib for untreated EGFR-positive metastatic non-small-cell lung cancer (terminated appraisal)		✓		The formulary will reflect the TAG – NHS England is the responsible commissioner (NICE unable to make a recommendation).
TA636: Eculizumab for treating refractory myasthenia gravis (terminated appraisal)		✓		The formulary will reflect the TAG – NHS England is the responsible commissioner (NICE unable to make a recommendation).
TA637: Ranibizumab for treating diabetic retinopathy (terminated appraisal)		✓		The formulary will reflect the TAG – NHS England is the responsible commissioner (NICE unable to make a recommendation).
TA638: Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA639: Atezolizumab with nab-paclitaxel for untreated PD-L1-positive, locally advanced or metastatic, triple-negative breast cancer	✓ R			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				
None				
7) Miscellaneous decisions by the APC				
GTN 0.4% Ointment for Rectal Fissures	✓ G			CCG commissioned tariff included drug. **Decision:** Change from AMBER SI to GREEN drug.
Toujeo Doublestar Insulin Pen		✓		CCG commissioned tariff included drug. Toujeo Solostar Insulin listed on formulary as AMBER SI. There is risk of errors as products are similar in name but dose administer is different. **Decision:** Add to formulary as NOT APPROVED.
Telotristat		✓		NHS England is the responsible commissioner. NHSE Policy Feb 2020: Not for Routine Commissioning Policy for Telotristat for treating carcinoid syndrome diarrhoea in adults **Decision:** Add to formulary as NOT APPROVED.
Saxagliptin – removal from formulary				CCG commissioned tariff included drug. **Decision:** removed from formulary for new patients due to minimal use in secondary and primary care. Existing patient stabilised on saxagliptin can remain on it. Currently formulary First Choice= Alogliptin. Alternatives =Sitagliptin and Linagliptin.
Alfentanil 5mg/ml injection – palliative care use.				CCG commissioned tariff included drug. Following recent prescribing error there should be no prescribing of Alfentanil 5mg/ml injection in primary care. Alfentanil 5mg/ml injection should only be used in Critical Care or Theatres. **Decision:** Removed from formulary for palliative care use.
Omeprazole suspension	✓			CCG commissioned tariff included drug. Licensed product now available. **Decision:** Change current formulary entry to the licensed 2mg/ml product and deleting the unlicensed 20mg/5ml strength.

DECISION SUMMARY

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

- CD&T APC Primary Care Guidance for Prescribing and Monitoring Post Bariatric Surgery
- CD&T APC Do Not Prescribe/Grey List – reviewed & updated
- County Durham & Darlington DVT pathway – reviewed & updated
- CD&T APC Position Statement on Omega-3 Prescribing
- CD&T APC Pain Management Guidance for Non-Cancer Pain in Primary Care
- CD&T APC Adult Asthma Guidelines – minor updates since July 2020
- CD&T APC Paediatric Asthma Guidelines – minor updates since July 2020
- CD&T APC COPD Guidelines – minor updates since July 2020

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

- CD&T Formulary Subgroup Terms of Reference – updated.