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 May 2022**

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 & 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				
None				
3) New formulations & extensions to use				
None				
4) Products considered by NICE				
TA762: Olaparib for treating BRCA mutation-positive HER2-negative metastatic breast cancer after chemotherapy (terminated appraisal)	✓ ✕			The formulary will reflect the TAG – NHS England is the responsible commissioner. (NICE unable to make a recommendation).
TA763: Daratumumab in combination for untreated multiple myeloma when a stem cell transplant is suitable	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA764: Fremanezumab for preventing migraine	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner

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TA765: Venetoclax with azacitidine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA766: Pembrolizumab for adjuvant treatment of completely resected stage 3 melanoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA767: Ponesimod for treating relapsing–remitting multiple sclerosis	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA768: Upadacitinib for treating active psoriatic arthritis after inadequate response to DMARDs	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner
TA769: Palforzia for treating peanut allergy in children and young people	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner Expected to be prescribed by NuTH only as the tertiary centre regionally for immunology. NuTH are in discussions with the CCG/ICS as the commissioners. Note: above the financial threshold for decision making of the APC so subject to final sign off from CCG executive committees.
TA770: Pembrolizumab with carboplatin and paclitaxel for untreated metastatic squamous non-small-cell lung cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA771: Daratumumab with bortezomib, melphalan and prednisone for untreated multiple myeloma (terminated appraisal)	✓ ✗			The formulary will reflect the TAG – NHS England is the responsible commissioner. (NICE unable to make a recommendation).
TA772: Pembrolizumab for treating relapsed or refractory classical Hodgkin lymphoma after stem cell transplant or at least 2 previous therapies	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
HST17: Odevixibat for treating progressive familial intrahepatic cholestasis	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
NG28 Type 2 diabetes in adults: management (updated)			✓	Review diabetes formulary chapter to assess whether action is required. Local Algorithm for the Management of Type 2 Diabetes will require updating and that NTAG are working with Diabetes Nework to do this once for the region.

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TA773: Empagliflozin for treating chronic heart failure with reduced ejection fraction	✓ ASI			The formulary will reflect the TAG – CCG is the responsible commissioner. Add to formulary as a SPECIALIST INITIATION drug for this indication.
TA774: Lenalidomide for relapsed or refractory mantle cell lymphoma (terminated appraisal) Commissioner: NHSE	✓ ✗			The formulary will reflect the TAG – NHS England is the responsible commissioner. (NICE unable to make a recommendation).
TA775: Dapagliflozin for treating chronic kidney disease	✓ G			The formulary will reflect the TAG – CCG is the responsible commissioner. Note: above the financial threshold for decision making of the APC so subject to final sign off from CCG executive committees.
TA776: Pitolisant hydrochloride for treating excessive daytime sleepiness caused by obstructive sleep apnoea	✓ ✗			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA777: Solriamfetol for treating excessive daytime sleepiness caused by obstructive sleep apnoea	✓ ✗			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA778: Pegcetacoplan for treating paroxysmal nocturnal haemoglobinuria	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA779: Dostarlimab for previously treated advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA780: Nivolumab with ipilimumab for untreated advanced renal cell carcinoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA781: Sotorasib for previously treated KRAS G12C mutation-positive advanced non-small-cell lung cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA782: Tagraxofusp for treating blastic plasmacytoid dendritic cell neoplasm (terminated appraisal)	✓ ✗			The formulary will reflect the TAG – NHS England is the responsible commissioner. (NICE unable to make a recommendation).
HST18: Atidarsagene autotemcel for treating metachromatic leukodystrophy	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner. Note tertiary centre only.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
5) Appeals against earlier decisions by the APC				
None				
6) Products considered by NTAG				
i-Port Advance® for use in children and adults with Type 1 diabetes	✓			Reviewed & no changes made. The formulary will reflect the NTAG position.
Infliximab subcutaneous injection (Remsima SC ®)	✓			Reviewed & no changes made. The formulary will reflect the NTAG position
Actipatch® for management of localised musculoskeletal pain	✓			Reviewed & no changes made. The formulary will reflect the NTAG position
Alfapump® device for ascites due to liver cirrhosis pain -	✓			Reviewed & no changes made. The formulary will reflect the NTAG position
Pitolisant (Wakix®) for the treatment of narcolepsy with or without cataplexy in adults	✓			Updated to reference NICE TA for Solriamfetol. The formulary will reflect the NTAG position.
Ulipristal (Ellaone®) for post-coital (up to 120 hours) contraception	✓			Reviewed and added links to FSRH Guidance. No other changes made. The formulary will reflect the NTAG position.
Solriamfetol for narcolepsy in adults	✓			Superseded NICE TA available The formulary will reflect the NTAG position.
7) Miscellaneous decisions by the APC				
Liothyronine Capsules	✓ **ASI**			CCG Commissioned, tariff included drug. Capsules were licensed on basis they were bioequivalent. Liothyronine is currently an AMBER SI drug on the formulary as per RMOC guidance. **Decision:** Add to formulary as an AMBER SI drug as additional option to tablets with note that capsules are more cost effective.
Tadalafil for pulmonary hypertension	✓ **R**			NHSE Commissioned, tariff excluded drug. **Decision:** Add Tadalafil for Pulmonary Hypertension to the formulary as a RED drug as per NoT formulary which is the tertiary centre.
Risperidone oral solution	✓ **ASI**			CCG Commissioned, tariff included drug. New Optimise Rx message directing prescribers away from using expensive risperidone orodispersible tablets and to use the 1mg/1ml oral solution if required. **Decision:** Add Risperidone oral liquid to the formulary as addition to orodispersible tablets as AMBER SI.
Valganciclovir	✓ **R**			NHSE Commissioned, tariff excluded drug. **Decision:** no change to remain RED on the formulary. This mirrors formulary position in North of Tyne.

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Estriol cream Estriol 0.01% w/w (Gynest) Ovestin 1mg estriol in 1g cream (0.1% cream)	✓ G			CCG Commissioned, tariff included drug. Two types of Estriol cream are available, and currently both are included in the CDTV formulary for their licensed indications (both GREEN drugs). Estriol cream is also recommended in NICE recurrent UTI guidance (NG112) for "off label" use in post-menopausal women to reduce recurrent UTIs, however recommendations on which product to prescribe are not given. Due to the amount that is given per dose, the recommended total mg of application for the two products is the same, however the 0.1% cream is 10x cheaper. **Decision:** approve the addition to formulary for use off label in recurrent UTI and to reclassify the more expensive Gynest to green alternative to encourage cost effective use.
Dihydrocodeine Tartrate 30mg Tablets	✓ R			CCG Commissioned, tariff included drug. CDTV pain guidance states that dihydrocodeine is not recommended for regular use (either alone or in combination with paracetamol as co-dydramol) in acute pain as it has a shorter half-life, and the effects are more likely to lead to abuse. Codeine is the preferred weak opioid analgesic. Dihydrocodeine is only approved for use in North of Tyne formulary in breast feeding mothers immediately postdelivery/ c-section where adequate pain relief has not been achieved using paracetamol and NSAIDs. Patients requiring continuation of dihydrocodeine following discharge (post-delivery/c-section) can have dihydrocodeine prescribed in primary care (for short-term use only). **Decision:** Change from Green Alternative to RED drug as per North of Tyne formulary position for use in breast-feeding mothers
Utrogestan® vaginal 200mg capsules	✓ ASI			CCG Commissioned, tariff included drug. This is the product included in the NICE guidance NG126: Ectopic pregnancy and miscarriage: diagnosis and initial management, and update in November 2021 on the use of progesterone in threatened miscarriage (unlicensed indication) NG126 states: Offer vaginal micronised progesterone 400 mg twice daily to women with an intrauterine pregnancy confirmed by a scan, if they have vaginal bleeding and have previously had a miscarriage. [2021]. If a fetal heartbeat is confirmed, continue progesterone until 16 completed weeks of pregnancy. **Decision:** Add Utrogestan® vaginal 200mg capsules to the formulary as AMBER SI with secondary care giving first 4 weeks of treatment and then writing to GP to confirm course length.

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

- TEWV Bipolar disorder under 18s prescribing tips
- CD&T APC Vitamins and Minerals Guidance – reviewed & updated

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

- DMARD Shared Care Guidelines – extension of review date: agreed that any shared care guidelines (SCGs) which have passed their review date will remain in use until an updated CDTV APC approved version is available, with only technical updates to address any emerging safety issues. The responsibility for developing and updating SCGs currently lies with the originating trusts, along with CDTV APC, but may be superseded by the adoption of national shared care templates. The review dates for the DMARD shared care guidelines were extended for a further six months in April 2022, as the national RMOC shared care guidelines are not yet available but expected very soon.

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

- CD&T APC Annual Report 2021/22