

County Durham & Tees Valley Area Prescribing Committee

Summary of decisions made regarding new product requests considered via email in **January 2021 and approved via Chair's Action on 2nd February 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 & 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 meeting				
None				
2) New Requests				
Ivacaftor + Tezacaftor + Elexacaftor (Kaftrio®) for Cystic Fibrosis	✓ R			NHSE commissioned tariff excluded drug. Decision: approved as a RED drug for the treatment of Cystic Fibrosis as per NHSE commissioning policy.
Low dose naltrexone for Hailey Hailey disease	✓ R			Unlicensed drug and indication. No cost impact for CCGs as tariff included drug and costs to be retained in secondary care. Decision: approved as RED drug with the cost being retained by the Trust (i.e. drug cost met from secondary and not recharged to CCG). There is some limited evidence from case reports to support use.
3) New formulations & extensions to use				
None				

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	Approved	Refused	Deferred	
4) Products considered by NICE				
HST13: Volanesorsen for treating familial chylomicronaemia syndrome	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA652: Apelisib with fulvestrant for treating hormone-receptor positive, HER2-negative, PIK3CA-positive advanced breast cancer (terminated appraisal)				The formulary will reflect the TAG – NHS England is the responsible commissioner (NICE unable to make a recommendation).
TA653: Osimertinib for treating EGFR T790M mutation-positive advanced non-small-cell lung cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA654: Osimertinib for untreated EGFR mutation-positive non-small-cell lung cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA655: Nivolumab for advanced squamous non-small-cell lung cancer after chemotherapy	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA656: Siponimod for treating secondary progressive multiple sclerosis	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA657: Carfilzomib for previously treated multiple myeloma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA658: Isatuximab with pomalidomide and dexamethasone for treating relapsed and refractory multiple myeloma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA659: Galcanezumab for preventing migraine	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner. (Note referred to CCG Exec committees for ratification as above financial limit for delegated authority of APC).
TA660: Darolutamide with androgen deprivation therapy for treating hormone-relapsed non-metastatic prostate cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA661: Pembrolizumab for untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.

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	Approved	Refused	Deferred	
TA662: Durvalumab in combination for untreated extensive-stage small-cell lung cancer (terminated appraisal)				The formulary will reflect the TAG – NHS England is the responsible commissioner (NICE unable to make a recommendation).
5) Appeals against earlier decisions by the APC				
None				
6) Products considered by NTAG				
None				
7) Miscellaneous decisions by the APC				
LHRH analogues for Prostate Cancer	✓ A			CCG commissioned tariff included drug. Decision: List all three drugs on the formulary with leuprorelin 3 monthly (Prostap DCS) as preferred first choice.
Sapropterin for phenylketonuria for non-pregnancy use.				NHSE commissioned tariff excluded drug. Decision: Sapropterin not approved for non-pregnancy use as per NHSE Interim Clinical Commissioning Policy for Sapropterin for phenylketonuria [200805P] (URN 1840).
Valaciclovir 250mg and 500mg tablets for Herpes Simplex and Varicella-zoster Infection	✓ G			CCG Commissioned, tariff included drug Decision: approved change of RAG status on the formulary from RED to GREEN. It is included as an alternative option to aciclovir in NICE antimicrobial prescribing guidance for infections that would commonly be managed in primary care. Use for the treatment of CMV would remain RED. Change from RED to GREEN drug for management of Herpes Simplex and Varicella-zoster Infection.
Desogestrel 75 microgram progesterone only contraceptive tablets	✓			CCG Commissioned, tariff included drug. Decision: Currently the CDTV formulary recommends using the cheapest brand, however agreed that this should be altered to advise that most patients are prescribed generically. Some generic desogestrel products contain soya and nut and are therefore not appropriate for allergy patients, therefore suggest consider changing wording as follows; <i>Prescribe generically in most cases. NB consider prescribing by brand in patients with soya or nut allergy as some generics may contain ingredients unsuitable for soya or nut allergy sufferers - check individual SPC.</i>

DECISION SUMMARY

The following guidelines were presented to and approved via email/APC Chair's Action in January 2021 by the APC:

- TEWV PHARM-0105-v1.1-Clozapine on admission to an acute hospital - safety guidance.

The following shared care guidelines were presented to and approved via email APC Chair's Action in January 2021 by the APC:

- TEWV PHARM-0024-v8 Safe Lithium Therapy Shared Care Guidelines
- TEWV PHARM-0027-v5 Methylphenidate - Shared care guidelines
- TEWV PHARM-0028-v5 Atomoxetine – Shared Care Guidelines
- TEWV PHARM-0025-v4.1 Melatonin Shared Care Guideline Dec 20 update – updated to include recent approval by TEWV stakeholder APCs/MCC of Slenyto® for its licensed indication only.

Other documents presented to and approved via email APC Chair's Action I in January 2021 by the APC:

- Nil.