

County Durham & Tees Valley Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Thursday 8th July 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 & 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				
Chloroprocaine Hydrochloride 1% Injection	✓ R			CCG commissioned tariff included drug. For Spinal anaesthesia in adults where the planned surgical procedure should not exceed 40 minutes. The existing spinal anaesthetic drugs are hyperbaric solutions and have the risk of hypotension and need prolonged monitoring in recovery. Decision: To add to formulary as a RED drug.
Nystatin 100,000 Pessaries (unlicensed)	✓ R			CCG commissioned tariff included drug. Requested as per BASHH guidelines for non-albicans vulvovaginal candida or in azole resistance. Decision: To add to formulary as a RED drug.
Epiduo® Gel 0.3% (Adapalene/Benzyl Peroxide)	✓ G			CCG commissioned tariff included drug. New strength for moderate to severe acne. Epiduo 0.1% available already for mild to moderate acne and listed on the formulary as a GREEN drug. Decision: To add to formulary as a GREEN drug. Use lower strength for mild to moderate acne and reserve higher strength for more severe acne.

DECISION SUMMARY

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Diamorphine pre-filled syringes (unlicensed)	✓ R			CCG commissioned tariff included drug. For use in spinal anaesthesia. To reduce the risk of errors around the mixing of drugs for spinal anaesthesia. Decision: To add to formulary as a RED drug.
3) New formulations & extensions to use				
None				
4) Products considered by NICE				
TA689: Acalabrutinib for treating chronic lymphocytic leukaemia	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA690: Teduglutide for treating short bowel syndrome (terminated appraisal)	✓			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA691: Avelumab for untreated metastatic Merkel cell carcinoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA517 Avelumab for treating metastatic Merkel cell carcinoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA692: Pembrolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy	✓ X			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA693: Olaparib plus bevacizumab for maintenance treatment of advanced ovarian, fallopian tube or primary peritoneal cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA694: Bempedoic acid with ezetimibe for treating primary hypercholesterolaemia or mixed dyslipidaemia	✓ G			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA695: Carfilzomib with dexamethasone and lenalidomide for previously treated multiple myeloma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA696: Tafamidis for treating transthyretin amyloidosis with cardiomyopathy	✓ X			The formulary will reflect the TAG – NHS England is the responsible commissioner.

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TA697: Andexanet alfa for reversing anticoagulation from apixaban or rivaroxaban	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA698: Ravulizumab for treating paroxysmal nocturnal haemoglobinuria	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA699: Ofatumumab for treating relapsing multiple sclerosis	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA700: Selinexor with low-dose dexamethasone for treating refractory multiple myeloma (terminated appraisal)	✓			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA701: Crisaborole for treating mild to moderate atopic dermatitis in people 2 years and older (terminated appraisal)	✓			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA702: Ibrutinib with obinutuzumab for untreated chronic lymphocytic leukaemia and small lymphocytic lymphoma (terminated appraisal)	✓			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA703: Ibrutinib with rituximab for untreated chronic lymphocytic leukaemia (terminated appraisal)	✓			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA704: Trastuzumab deruxtecan for treating HER2-positive unresectable or metastatic breast cancer after 2 or more anti-HER2 therapies	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
5) Appeals against earlier decisions by the APC				
None				
6) Products considered by NTAG				
None				

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7) Miscellaneous decisions by the APC				
Procyclidine 5mg/5ml oral liquid	✓ A			CCG commissioned tariff included drug. Rosemont now also make a licensed 5mg/5ml which is more cost effective for larger doses. 2.5ml/5ml liquid currently listed as Amber SI on the formulary. Both products are licensed for the same indications. Decision: To add this strength to formulary as additional strength.
Simple Eye Ointment	✓			CCG commissioned tariff included drug. To remove simple eye ointment from the formulary due to cost. Other significantly cheaper eye ointment used as ocular lubricants are available on the County Durham & Tees formulary. Decision: To remove from formulary.
Hydrocortisone sodium phosphate 100mg/ml IM Injection (Efcortisol)	✓ G			CCG commissioned tariff included drug. Requested as an additional option to hydrocortisone sodium succinate for patients who are steroid dependant (pituitary or adrenal cause and occasionally non-endocrine reasons for long term steroid use) to manage sick day rules to avoid an Addisonian crisis. Efcortisol is currently listed as not approved because the BNF lists as less suitable for prescribing as Paraesthesia and pain may follow intravenous injection. Decision: To change from NOT APPROVED to a GREEN drug as an additional option to hydrocortisone sodium succinate for patients who are steroid dependant (pituitary or adrenal cause and occasionally non-endocrine reasons for long term steroid use) to manage sick day rules to avoid an Addisonian crisis.
Denosumab 60mg injection (Prolia®)	✓ A			CCG commissioned tariff included drug. Decision: To change wording on formulary to make clear that AMBER Specialist Initiation with first dose being given in secondary care.
Fulvestrant injection	✓ R			NHSE commissioned tariff excluded drug Decision: To change from NOT APPROVED to RED for those NICE TAs that permit use in combination with other agents (i.e. TA579, 619 & 687)

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Bosentan for digital ulcers	✓ R			<p>NHSE commissioned tariff excluded drug</p> <p>Formulary currently states that: NHS England – Not Routinely Commissioned for digital ulcers. There has been a change in NHSE policy Clinical Commissioning Policy: Sildenafil and Bosentan for the Treatment of Digital Ulceration in Systemic Sclerosis in adults Reference: NHS England 210302P. NHS England will now commission sildenafil and bosentan for patients requiring treatment of digital ulceration in systemic sclerosis in adults.</p> <p>Decision: To add to formulary as RED for digital ulcers as per updated NHSE commissioning policy.</p>
Isosorbide Mononitrate 60mg MR tablets	✓ G			<p>CCG commissioned tariff included drug.</p> <p>Modified release preparation requested for when compliance issues with ordinary twice daily tablets. Various modified release strengths already currently being prescribed. 60mg MR tablets chosen as the one most commonly prescribed and this is what is on formulary in Sunderland, NoT and York & Scarborough. Also tablets can be halved to give a 30mg dose if needed</p> <p>Decision: To add to formulary as a GREEN drug only when non-modified release are unsuitable e.g. to improved compliance.</p>

The following guidelines were presented to and approved at the July 2021 meeting of the APC:

- TEWV STOMP medication pathway
- TEWV Depression pathway (updated): updated version approved.
- TEWV Anxiety pathway (updated): updated version approved.
- TEWV Adult ADHD algorithm (updated): updated version received for information.
- TEWV Childrens ADHD algorithm (updated): updated version received for information.
- CD&T Dapagliflozin for Heart Failure Guideline
- CD&T Guidance for Prescribing & Monitoring Post Bariatric Surgery – updated
- CD&T Gluten Free Guidance – reviewed & updated
- County Durham bladder and bowel formulary – reviewed & updated
- UACR Flowchart
- GP clinical information sheet to support the prescribing and monitoring of Denosumab (Prolia®)
- Amendment to CD&D DVT Pathway – to increase initial quantity of tablets supplied.
- Updates to CD&T Respiratory Guidelines (COPD, Asthma, Paediatric Asthma)
- County Durham Monitored Dosage System Guidance

The following shared care guidelines were presented to and approved at the July 2021 meeting of the APC:

- Ergot derived dopamine agonists SCG – reviewed and no changes made.
- Tolcapone in Parkinson's SCG – reviewed and no changes made.

Other documents presented to and approved at the July 2021 meeting of the APC:

- CD&T APC Clinical Guideline or Pathway Approval Checklist.