County Durham & Tees Valley Area Prescribing Committee

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Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Thursday 9th January 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				
Iron Isomaltoside (Monofer®) injection	✓ R			Requested by CDDFT. Iron Sucrose (venofer), Iron Dextran (Cosmofer) and Ferric Carboxymaltose (Ferrinject) already listed on the formulary as RED drugs. Addition of Monofer may offer some benefits in terms of reduced infusion time and some cost savings to Trusts, and will allow Trusts a choice of their preferred product. **Decision:** approved in addition to existing IV iron formulations already included in the formulary.
Budesonide (Cortiment® 9mg prolonged release tablets in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where 5-ASA treatment is not sufficient.	✓ R			Requested by CDDFT. Budesonide capsules are not licensed for this indication and there is no evidence to support drug delivery to distal colon at the site of disease, and therefore the drug may not be effective in the capsule form for this indication. A licensed treatment should be used where available. **Decision:** approved as 2nd line treatment – where 5-ASA treatment alone has not induced remission of symptoms, and patients have a clinical need for corticosteroid treatment to induce remission of colitis. Approved as RED as 8 week treatment course.

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Bictegravir 50mg/ Emtricitabine 200mg/ Tenofovir alafenamide fumarate 25mg Film coated tablets (Biktarvy®) for the treatment of adults with HIV-1	✓ R			Requested by STHFT. NHSE approved and commissioned for this indication. **Decision:** approved
Human pappilomavirus 9-valent vaccine (Gardasil 9®) for Recurrent Laryngeal Papillomatosis (unlicensed indication)	✓ R			Requested by STHFT. British Laryngological Association and STHFT D&T support use as RED drug for use in patients with refractory laryngeal papillomatosis requiring frequent surgical procedures to control. Severe cases may need surgery repeating every 6 weeks with a 2 week healing period also affecting the voice. More surgeries means more risk and more long term scarring **Decision:** approved for this indication as per British Laryngological Association guidance.
Zanamivir 10mg/ml solution for infusion (Dectova®) (20ml vials) for the treatment of complicated and potentially life-threatening influenza A or B virus infection in adult and paediatric patients (aged ≥6 months)	✓ R			Requested by STHFT. New licensed formulate, previously only free compassionate use unlicensed injection available. The intravenous route will primarily be used when other presentations are not suitable for patients e.g. on intensive care where cannot use inhaled zanamivir or not absorbing medications (or high degree of suspicion). **Decision:** approved. Would only be used after approval of infectious disease or microbiology in accordance with official guidance from PHE.
3) New formulations & extensions to use				
None				
5) Products considered by NICE				
TA604: Idelalisib for treating refractory follicular lymphoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA605: Xeomin (botulinum neurotoxin type A) for treating chronic sialorrhoea	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA606: Lanadelumab for preventing recurrent attacks of hereditary angioedema	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA607: Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease	✓ A			The formulary will reflect the TAG – CCG is the responsible commissioner.

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TA608: Ibrutinib with rituximab for treating Waldenstrom's macroglobulinaemia (terminated appraisal)	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA609: Ramucirumab for treating unresectable hepatocellular carcinoma after sorafenib (terminated appraisal)	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA610: Pentosan polysulfate sodium for treating bladder pain syndrome	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA611: Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA612: Neratinib for extended adjuvant treatment of hormone receptor-positive, HER2-positive early stage breast cancer after adjuvant trastuzumab	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA613: Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema in phakic eyes after an inadequate response to previous therapy		✓		The formulary will reflect the TAG – CCG is the responsible commissioner. (Not recommended by NICE)
HST11: Voretigene neparvovec for treating inherited retinal dystrophies caused by RPE65 gene mutations				No further action. Highly specialist. No centres in North-East.
HST12: Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2				No further action. Highly specialist. No centres in North-East.
7) Appeals against earlier decisions by the APC				
None				
8) Products considered by NTAG				
None				

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
8) Miscellaneous decisions by the APC				
Methadone in palliative care	✓ A			Currently on formulary following harmonisation process as RED status which is creating some unnecessary and unintended barriers to appropriate prescribing in palliative care. **Decision:** approved change from RED to AMBER Specialist Initiation/Recommendation with note that use in pain management should be under the advice of palliative care
Renavit	✓ A			Request from renal team at Sunderland to review RED RAG status for Renavit in new harmonised formulary. In Sunderland classed as GREEN+. Previously on formulary in STHFT with no RAG status. **Decision:** approved change from RED to AMBER Specialist Initiation/Recommendation for Renal dialysis patients only
Review of oral Mesalazine brands currently included in formulary	✓ G			Current brands on formulary are Asacol, Pentasa and Mezavant XL plus Octasa 400mg. At present the Octasa 800mg and 1600mg tablets are not available of formulary so if a patient is not willing to take that many tablets, an alternative brand of mesalazine would require to be used to ensure compliance. Salofalk offers the option of sachets for patients unable to swallow tablets/passing whole tablets and is a cheaper option than Pentasa sachets. Pentasa is required on formulary for patients who have disease that begins in the terminal ileum as is the only formulation to begin release at this point. As Asacol suppositories are no longer available the addition of Salofalk suppositories is necessary as having only one suppository on formulary leads to issues during shortages. **Decision:** • Asacol to be removed from formulary as Octasa has replaced this, those patients on this historically can remain on Asacol but no new patients to be commenced on Asacol. • To add all formulations of Salofalk and Octasa to formulary. Salofalk available for new patients and those struggling with tablets / requiring a sachet formulation. • To retain Mezavant XL on formulary.
Lumacaftor/Ivacaftor and Tezacaftor/Ivacaftor for Cystic Fibrosis	✓ R			Requested as per NHSE Clinical Commissioning Urgent Policy Statement: Cystic Fibrosis Modulator Therapies NHS England URN: 190137P **Decision:** approved.
Melatonin oral solution 5mg/5ml Propylene glycol and alcohol free	✓ ASC			This the current oral liquid recommended in current local shared care guidelines but need to ensure only use if crushing Circadian tablets is not possible. It is only oral solution in the Drug Tariff which is known to be Propylene glycol and alcohol free. **Decision:** approved

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Aveeno cream	✓			Aveeno is not used or recommended by dermatology at STHFT or CDDFT. Zeroveen is considered the same and is less expensive. **Decision:** approved removal of Aveeno from formulary as part of further rationalisation of emollient products.
Progesterone pessaries – clarification for formulary status and indications approved for	✓ R			The current formulary entry is unclear. **Decision:** confirmed formulary status as RED for IVF use and to support the pregnancies of woman who have a history of miscarriage or premature labour as per NICE NG 25.
Apraclonidine 0.5% and 1% eye drops – clarification of formulary status and RAG status	✓			Apraclonidine (both strengths) is currently AMBER SI on the new formulary – in light of the differences in licensing for the 2 strengths, CCGs have asked is it possible to add some wording to the formulary to clarify this and also to add info about maximum duration of treatment. **Decision:** • Both 0.5% and 1% to remain as AMBER Specialist Initiation when used off-label in complex glaucoma when all other options failed to preserve sight on unlicensed basis • 0.5% when used as per license prior to laser treatment or surgery to be RED. • 1% when used as per license in Theatre to be RED.
Eflornithine cream – clarification of current RAG status	✓ R			Eflornithine is showing as AMBER SI/SR on the new harmonised formulary –it was previously RED in Tees only to be used in combination with laser therapy, and Green+ in CD&D There is no evidence of its efficacy in comparison to existing treatments and it is substantially more expensive. It needs to be used indefinitely but the long-term benefits and safety have not been established. **Decision:** confirmed formulary status as RED and to be used only in line with laser therapy.
Torasemide – review of formulary status		✓		Six clinical studies are cited to support the use over bumetamide/furosemide all have methodological or quality issues which limit their validity and/or generalisability. There is therefore not sufficient evidence to establish that torasemide is superior or inferior to furosemide for any outcome. **Decision:** to remain as non-formulary.
Tapentadol – review of formulary status	✓ A			**Decision:** to remain as AMBER specialist initiation on formulary as 3rd line treatment for the relief of severe chronic pain in adults which can be adequately managed only with opioid analgesics AND in whom morphine and oxycodone has failed to provide adequate pain relief or is not tolerated. It is for chronic pain team use only not for acute pain team use.Need to ensure patients are followed up by chronic pain team.

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Midodrine for use in postural hypotension	✓ A			Previously Green+ in CD&D and AMBER Shared Care in Tees. **Decision:** approved change care to formulary as AMBER specialist initiation as no specific monitoring requirements other than BP.
Tolvaptan (Samsca® for non-chemo related SIADH	✓ R			**Decision:** approved as RED for max 10 day course and not for long term use. This reflects how the product is currently used in secondary care and the status in Sunderland and North of Tyne.
Triptorelin	✓ A			All other LHRH analogues in Tees and CD&D are listed as AMBER SI. It is Green+ for precocious puberty in the North of Tyne formulary. **Decision:** approved as Amber Specialist Initiation for all indications including precocious puberty
Flumetasone 0.02% with Clioquinol 1% for Otitis Externa	✓ G			Not included in formulary due supply issues but now available again. **Decision:** approved as GREEN drug.
Chloral Hydrate 1g/5mL oral solution	✓ R			Recommended strength in children as per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children. STHFT, CDDFT and NTHFT already adopted this guidance. **Decision:** add to formulary 1g/5ml as RED drug with note that standard strength recommended by RCPCH in children. To remove 500mg/5ml from formulary.
Clopidogrel 25mg/5mL oral solution		✓ ✗		Recommended strength in children as per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children. STHFT, CDDFT and NTHFT already adopted this guidance. **Decision:** Do not add to local formulary as local prescribing data does indicate any specials of clopidogrel currently used. Also not on NoT APC formulary.
Hydrocortisone 5mg/5mL oral solution	✓ A			Recommended strength in children as per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children. STHFT, CDDFT and NTHFT already adopted this guidance. **Decision:** Add this strength to formulary as AMBER SI with note that standard strength recommended by RCPCH in children. To Retain 10mg/5ml for now as used NoT and in adults.
Omeprazole 20mg/5ml oral solutions	✓ A			Recommended strength in children as per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children. STHFT, CDDFT and NTHFT already adopted this guidance. **Decision:** Add this strength to formulary as AMBER SI with note that standard strength recommended by RCPCH in children. To be only for children with narrow bore feeding tubes or those requiring a dose <5mg. Lansoprazole fast tabs or omeprazole MUPS should be used in all other patients.

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Phenobarbital (alcohol free) 50mg/5mL oral solution	✓ **A**			Recommended strength in children as per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children. STHFT, CDDFT and NTHFT already adopted this guidance. **Decision:** replace 20mg/ml with 50mg/5ml strength with note that standard strength recommended by RCPCH in children.
Sertraline 50mg/5mL oral solution	✓ **A**			Recommended strength in children as per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children. STHFT, CDDFT and NTHFT already adopted this guidance. **Decision:** add 50mg/5ml as AMBER SI to formulary with note that standard strength recommended by RCPCH in children.
Sodium chloride 5mmol/mL oral solution **(N.B. 1mmol/ml currently on formulary = licensed product)**	✓ **A**			Recommended strength in children as per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children. STHFT, CDDFT and NTHFT already adopted this guidance. **Decision:** Add to formulary 5mmol/ml as AMBER SI with note that standard strength recommended by RCPCH in children. Retain 1mmol/ml for now as licensed product.
Spironolactone 50mg/5mL oral liquid	✓ **A**			Recommended strength in children as per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children. STHFT, CDDFT and NTHFT already adopted this guidance. **Decision:** add to formulary with note that standard strength recommended by RCPCH in children. Remove 5mg/5ml, 25mg/5ml and 100mg/5ml from formulary. Retain 10mg/5ml as in NoT formulary
Tacrolimus 5mg/5ml oral liquid 8.2.2 As per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children.	✓ **R**			Recommended strength in children as per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children. STHFT, CDDFT and NTHFT already adopted this guidance. **Decision:** add to formulary as RED drug with note that standard strength recommended by RCPCH in children
Antipsychotic depot injections	✓ **ASC**			Agreed to add sentence to formulary that "If the transfer of care was made prior to 11/7/2019 then this drug was considered as amber specialist initiation and does not need to be referred back to establish shared care. A shared care agreement is required for any transfer from 11/7/2019 onwards"

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

- RMOC Position Statement on Vitamin B Supplementation

The following shared care guidelines were presented to and approved at the January 2020 meeting of the APC:

- Tees Apomorphine in Parkinson's disease SCG
- Tees Tinzaparin in Obstetrics SCG

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

- APC Workplan 2020