County Durham & Tees Valley
Area Prescribing Committee

Summary of decisions made regarding new product requests considered via email in **January 2022 and approved via Chair's Action on .**

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 meeting				
None				
2) New Requests				
Insulin aspart (biosimilar) Trurapi® 100 units/mL solution for injection 3mL cartridges 100 units/mL solution for injection 3mL pre-filled Solostar pens	✓ G			CCG Commissioned, tariff included drug. Trurapi is indicated for the treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above. Available efficacy and safety data suggest that it is comparable to Novorapid, but its lower price makes it more cost effective Novorapid to remain on the formulary. **Decision:** To add to the formulary as a GREEN drug as an alternative to Novorapid. Novorapid to remain on the formulary.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Insulin lispro with citrate and treprostinil) (Lyumjev®)▼ Lyumjev 100 units/mL KwikPen® solution for injection in pre-filled pen Lyumjev 100 units/mL Junior KwikPen solution for injection in pre-filled pen1 Lyumjev 100 units/mL solution for injection in cartridge Lyumjev 100 units/mL solution for injection in vial		✓		CCG Commissioned, tariff included drug. Second rapid acting version of insulin lispro to be marketed in the UK. Lyumjev is indicated for the treatment of diabetes mellitus in adults only. This version is Humalog with the addition of treprostinil and citrate to faster absorption and onset of action. **Decision:** Not to add to formulary at this stage because unclear whether the difference in onset of action between Lyumjev and Humalog is clinically relevant, but timing of hypoglycaemia may be clinically important. The only other apparent difference between Lyumjev and Humalog is the increase in injection site reactions. Also concern that could lead to wider use leading to increased costs compared to lispro biosimilars. There is already one other ultra-rapid mealtime insulin available on the formulary (Insulin aspart – Fiasp®). There have been no comparative studies of Fiasp vs. Lyumjev.
3) New formulations & extensions to use				
None				
4) Products considered by NICE				
TA732: Baloxavir marboxil for treating acute uncomplicated influenza (terminated appraisal)	✓ ✗			The formulary will reflect the TAG – NHS England is the responsible commissioner (NICE unable to make a recommendation).+
TA733: Inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia	✓ G			Listed as a GREEN drug in chapter 2.12 Discussed at and approved at Nov 2021 APC meeting The formulary will reflect the TAG – CCG is the responsible commissioner
TA734: Secukinumab for treating moderate to severe plaque psoriasis in children and young people	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA735: Tofacitinib for treating juvenile idiopathic arthritis	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA736: Nivolumab for treating recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based chemotherapy	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.

DECISION SUMMARY

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA737: Pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced oesophageal and gastro-oesophageal junction cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA738: Berotralstat for preventing recurrent attacks of hereditary angioedema	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA739: Atezolizumab for untreated PD-L1-positive advanced urothelial cancer when cisplatin is unsuitable	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA740: Apalutamide with androgen deprivation therapy for treating high-risk hormone-relapsed non-metastatic prostate cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA741: Apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA742: Selpercatinib for treating advanced thyroid cancer with RET alterations	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA743: Crizanlizumab for preventing sickle cell crises in sickle cell disease	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA744: Upadacitinib for treating moderate rheumatoid arthritis	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA745: NBTXR-3 for treating advanced soft tissue sarcoma (terminated appraisal)	✓ ✗			The formulary will reflect the TAG – NHS England is the responsible commissioner (NICE unable to make a recommendation).
TA746: Nivolumab for adjuvant treatment of resected oesophageal or gastro-oesophageal junction cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA747: Nintedanib for treating progressive fibrosing interstitial lung diseases	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
HST16: Givosiran for treating acute hepatic porphyria	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
5) Appeals against earlier decisions by the APC				
None				
6) Products considered by NTAG				
None				
7) Miscellaneous decisions by the APC				
Spironolactone for acne	✓ R			CCG Commissioned, tariff included drug. Requested for female patients intolerant of or not-responding to isotretinoin. It is unlicensed for this indication. **Decision:** Add to formulary as RED drug as unlicensed and to manage risks around pregnancy.
Trimbow® Nexthaler **Commissioning: CCG, tariff included**	✓ G			CCG Commissioned, tariff included drug. Now also available in a Nexthaler for COPD – this gives an alternative to MDI and is the same cost. **Decision:** Add to formulary and COPD guidelines as a GREEN drug.
Tiogiva® (Tiotropium) **Commissioning: CCG, tariff included**	✓			CCG Commissioned, tariff included drug. Respiratory CAG recommends that tiotropium is removed from guidelines, on the understanding that patients currently stable on tiotropium do not need to be changed, but that alternative choices are used for any new patients that would support easier transition when medication needs to be escalated **Decision:** to remove all tiotropium from guidelines as devices do not support easy transition to combined therapy when medication is escalated, and a number of patients do not have strong enough inspiratory flow to use the current devices. Annotate formulary to say Tiotropium in COPD should only be used for existing patients, and remove from COPD guidelines.
Luforbec® pMDI® for asthma / COPD **Commissioning: CCG, tariff included**	✓			CCG Commissioned, tariff included drug. Only available in lower strength so ould be confusing to prescribers and patients, and is a pMDI so does not support the movement to none MDI devices where clinically appropriate. **Decision:** Do not add to formulary or local COPD guidelines.
Danazol 100mg and 200mg capsules	✓			CCG Commissioned, tariff included drug. Now discontinued and there are no licensed products available. **Decision:** To delete from formulary as discontinued.
Melatonin for use in Parkinson's disease	✓			CCG Commissioned, tariff included drug. **Decision:** To clarify on formulary that current status melatonin (neurology use) = AMBER SI/SR includes in Parkinson's disease on the advice of any specialist.

DECISION SUMMARY

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Ipratropium Nebules	✓ A			CCG Commissioned, tariff included drug. Prior to merging the formularies Ipratropium nebules were Green on both County Durham formulary and the Tees Formulary. Was agreed to change to Red because no longer in local COPD guidelines and is usually given in hospital for asthma. **Decision:** To change status to "AMBER Specialist Initiation" following recent requests to prescribe in Tees Valley CCG.
Tadalafil Once Daily 5mg tablets for Benign Prostatic Hyperplasia	✓ ✗			CCG Commissioned, tariff included drug. Currently listed on formulary as NOT APPROVED for Benign Prostatic Hyperplasia: NICE terminated their technology appraisal (TA273) due to receiving no evidence from the manufacturer. In NICE CG97: Lower Urinary Tract Symptoms in Men NICE state that there is not enough evidence to recommend phosphodiesterase inhibitors in routine clinical practice. Also included in NHSE Items of Low Clinical Value Guidance. **Decision:** To remain as NOT APPROVED for Benign Prostatic Hyperplasia in the absence of erectile dysfunction until NICE or NHSE guidance is updated. To clarify on the formulary that tadalafil 5mg once daily tablets are approved if patient has erectile dysfunction alone OR erectile dysfunction and BPH.
Tadalafil 5mg Once daily tablets for erectile dysfunction	✓ G			CCG Commissioned, tariff included drug. **Decision:** Change once daily 5mg tadalafil from AMBER SI to GREEN as an option for the management of erectile dysfunction for patients the SLS criteria. Oral 2.5mg tadalafil is not recommended on the basis of cost.
Vardenafil	✓ G			CCG Commissioned, tariff included drug. After generic sildenafil and tadalafil prn, vardenafil currently is cheaper than avanafil. Currently more prescribing of Vardenafil in CD&T than avanafil even though it is non-formulary. **Decision:** Change Vardenfail from NOT APPROVED to GREEN ALT drug. .
Avanafil	✓ ✗			CCG Commissioned, tariff included drug. **Decision:** Change Avanafil from GREEN ALT to NOT APPROVED.
Dapagliflozin				**Decision:** removed indication for use Type 1 diabetes as NICE TA withdrawn and no longer licensed for this indication.

The following guidelines were presented to and approved via email/APC Chair's Action in January 2022 by the APC:

- CD&T Hypogonadism guidelines – minor amendment to include assessment for fracture risk.

The following shared care guidelines were presented to and approved via email APC Chair's Action in January 2022 by the APC:

- TEWV PHARM-0094-v1.1 Guanfacine - shared care guidelines updated Oct 21

Other documents presented to and approved via emai APC Chair's Action l in January 2022 by the APC:

- Nil.