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 March 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				
Midazolam 2mg/ml oral solution (Ozalin®)	✓ R			Requested by STHFT. This medication will be a Consultant only prescription for children requiring a Midazolam premedication, who have spat out Midazolam in the past, attended anxiety clinic or who have oral aversion/sensory syndromes where a bitter taste would not be tolerated. It will not be used as the routine Midazolam preparation. It is a licensed product for this indication (other oral solutions used off-label for this indication). **Decision:** approved as RED drug as an additional oral formulation of midazolam pre-medication for anxious children prior to anaesthesia. Decision subject to each Trust carry out their own risk assessment on the use of the product.
Tiopronin 100mg tablets	✓ R			Requested by STHFT as second line treatment for cystinuria in patients who fail to tolerate/respond to penicilliamine. It is unlicensed and imported from Japan. **Decision:** approved as RED drug as second line treatment for cystinuria after penicillamine

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Buprenorphine oral lyophilisate (Espranor®)		✓		Request comes from Spectrum CIC for use in the community following release from prison. North East Prison Cluster (NEPC) have approached all 3 APCs in the Region to ask for consideration of the introduction of Espranor onto community formularies on a restricted basis by the prison service only. Decision: Not approved. The FSG and APC came to this recommendation not to approve addition to the formulary because: • Concerns were expressed around patient safety implications including potential variation in bioavailability, confusion arising from multiple dosage forms of buprenorphine and the impact on community pharmacy supervised services – this was expressed previously by North of Tyne • Risk of dispensing errors in community pharmacies from having Espranor and SL forms both available when 2mg and 8mg strengths both available – people may not realise the products and dose are different. • NEPC policy is not to crush the SL preparation when crushing of SL preparations by prison services is supported in the Orange Guide. • Concerns around that Espranor use in the community could become difficult to monitor if added to formulary as may be creep in use outside of those released from prison. • FSG did not feel comfortable adding to formulary with sentence saying only for use following release from prison because of any stigma this might create unintentionally for those clients ie. Anyone dispensing a script for Espranor or involved in the care of someone on it in community would potentially know they are only on it as they have been in prison if they looked at formulary website. The implication of the recommendation not to approve addition to the formulary is that individuals released from prison will have to be immediately titrated onto a SL form of Buprenorphine by the community service. Therefore there will need to be a clear discharge process between NEPC and the community service.
Thickened feeds: Nutilis Complete Drink Level 3, Nutilis Complete Crème Level 3 and Nutilis Fruit Level 4	✓ **A**			Requested by NTHFT. **Decision:** approved AMBER Specialist Recommendation on the advice of SALT team/dietician only. Recommended on patient safety grounds to avoid thickening standard oral nutritional supplements due to the difficulties that can be encountered in thickening standard oral nutritional supplements.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
3) New formulations & extensions to use				
None				
5) Products considered by NICE				
TA614: Cannabidiol with clobazam for treating seizures associated with Dravet syndrome	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA615: Cannabidiol with clobazam for treating seizures associated with Lennox–Gastaut syndrome	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA616: Cladribine for treating relapsing–remitting multiple sclerosis	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA617: Lusutrombopag for treating thrombocytopenia in people with chronic liver disease needing a planned invasive procedure	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA618: Atezolizumab with carboplatin and nab-paclitaxel for untreated advanced non-squamous non-small-cell lung cancer (terminated appraisal)		✓		The formulary will reflect the TAG – CCG is the responsible commissioner. (NICE unable to make a recommendation)
TA619: Palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA620: Olaparib 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.
TA621: Osimertinib for untreated EGFR mutation-positive non-small-cell lung cancer		✓		The formulary will reflect the TAG – CCG is the responsible commissioner. (Not recommended by NICE)

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
7) Appeals against earlier decisions by the APC				
Fluticasone/Azelastine (Dymista® Nasal Spray: approved adding to formulary as GREEN drug for use in allergic and non-allergic rhinitis plus chronic rhinitis with an agreed pathway for use in place to support use.				Requested by STHFT for use for use in allergic and non-allergic rhinitis plus chronic rhinitis. **Decision:** approved as GREEN drug for use in allergic and non-allergic rhinitis plus chronic rhinitis with an agreed pathway for use in place to support use. To be used in primary care after failure of treatment with an intranasal steroid (INS) or antihistamine, or INS plus oral antihistamine prior to referral to secondary care. Use should be reviewed in primary care after three months and the Dymista® stopped if not working before considering referral to secondary care.
8) Products considered by NTAG				
None				
8) Miscellaneous decisions by the APC				
Tolcapone 100mg tablets	✓ ASC			**Decision:** Add to formulary as AMBER SC using Tees shared care guideline.
Choral Hydrate oral solution – change in strength recommended from 1g/5ml to 500mg/5ml	✓ R			**Decision:** To note that formulary has been updated to reflect a change in NPPG guidance which now recommends 500mg/5ml strength rather than 1g/5ml i.e. back to what was originally on the formulary before it was updated following January 2020 APC.
Nefopam 30mg tablets	✓ A			**Decision:** Add to formulary as AMBER specialist initiation for patient who are unable to tolerate opioids or where opioids are contra-indicated. To update and reissue position statement from Tees as an APC document: • don't initiate nefopam for acute or chronic pain in primary care • don't continue nefopam post-discharge following secondary care acute initiation • only continue nefopam in line with recommendations of the specialist pain service • review existing patients
Insuman Basal 5ml vial, Comb 25 5ml vial and Comb 15 Cartridge				These three presentations of Insuman Basal have been discontinued by the manufacturer. **Decision:** approved removal from the formulary.

DECISION SUMMARY

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Sativex® spray for spasticity in MS	✓			Cannabis-based medicinal products NICE guideline [NG144] Published date: November 2019 – change in NICE recommending use for spasticity in MS NICE have recommended that use in MS related spasticity will be initiated by specialists but may be transferred to primary care for prescribing under a shared care agreement. A formulary application is currently pending from the neurologists at STHFT. North of Tyne APC have recently approved as AMBER Shared Care. **Decision:** Interim position should be that Sativex® for spasticity in MS is RED until shared care in place as per current North of Tyne APC position.
Ingenol mebutate gel				EMA has suspended the license for suspends Picato® gel as a precaution while review of skin cancer risk continues. As a result the MHRA & manufacturer have issued a product recall. **Decision:** approved removal from the formulary.

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

- RMOC Position Statement on Vitamin B Supplementation
- RMOC Free of Charge Medicines Schemes.
- RMOC Advisory Statement: Sequential Use of Biologic Medicines
- TEWV Safe Transfer of Prescribing Guideline
- TEWV Dementia Treatment Algorithm
- TEWV Psychotropic Monitoring Guideline
- Position Statement on Nefopam
- Guidance for the Prescribing of Vitamins & Minerals in Primary Care in County Durham & Tees Valley
- Guideline for Self-Monitoring of Blood Glucose: reviewed and update guideline including local meter and test strip choices approved for local adoption by APC.

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

- TEWV Lisdexamfetamine SCG
- Melatonin SCG: minor update to remove reference to adults approved.
- County Durham & Darlington Methotrexate SCG