County Durham & Tees Valley
Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Thursday 14th November 2019**

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				
Menotrophin (Meriofert®) 75 unit and 150 unit powder and solvent for solution for injection	✓ R			Requested by STFHT as a replacement for Menopur® for use in IVF. **Decision:** agreed to list generically in formulary and allow Trusts to use their preferred brand.
Azelastine/ Fluticasone Nasal Spray (Dymista®)		✓		Requested by STFHT for allergic and non-allergic rhinitis/ CRS/ Asthma as a GREEN drug. No published clinical evidence in allergic rhinitis comparing Dymista® to use of a combination of a steroid nasal spray and an antihistamine tablet which is more common current practice. Concerns approval could lead to difficulty in ensuring prescribed appropriately and difficulty managing costs in this therapeutic area in primary care.First line treatment option should remain at OTC nasal spray plus an OTC antihistamine. **Decision:** not approved.

DECISION SUMMARY

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Mexiletine 167mg hard capsules (NaMuscla®)	✓ R			Requested by STHFT for myotonia in adults with non-dystrophic myotonic disorders. It was noted that this NHSE commissioned for this indication via Blueteq and that STHFT is one of the NHSE commissioned centres for us of this drug as per SSC2001. **Decision:** approved.
Pasireotide injection **300mircogram to 900microgram ampoules for subcutaneous injection** **10mg to 60mg vials for intramuscular injection**	✓ R			Requested by STHFT for Cushings Disease. It is a NHSE commissioned drug for this indication. It was noted that currently listed as NOT APPROVED approved on the formulary for Cushings disease but use was approved by change in NHSE commissioning policy from Dec 2016. **Decision:** change from NOT APPROVED to RED drug approved.
MCT Oil for resistant epilepsy		✓ ✗		Requested by STHFT for resistant epilepsy **Decision:** NOT APPROVED because the application was not approved at the Sept 2019 STHFT D&T as the evidence base is poor.
Sodium Hyaluronate injections for osteoarthritis of the knee		✓ ✗		Requested by NTHFT for osteoarthritis of the knee. **Decision:** NOT APPROVED as use not recommended as per NICE CG 177. Also noted the work already undertaken in CDDFT to stop use, and that NTHFT had rejected use of the drug previously.
3) New formulations & extensions to use				
None				
5) Products considered by NICE				
TA590: Fluocinolone acetonide intravitreal implant for treating recurrent non-infectious uveitis	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA591: Letermovir for preventing cytomegalovirus disease after a stem cell transplant	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA592: Cemiplimab for treating metastatic or locally advanced cutaneous squamous cell carcinoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.

DECISION SUMMARY

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	Approved	Refused	Deferred	
TA593: Ribociclib 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.
TA594: Brentuximab vedotin for untreated advanced Hodgkin lymphoma (terminated appraisal)	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA595: Dacomitinib for untreated EGFR mutationpositive non-small-cell lung cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA597: Dapagliflozin with insulin for treating type 1 diabetes	✓ A			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA598: Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA600: Pembrolizumab with carboplatin and paclitaxel for untreated metastatic squamous nonsmall-cell lung cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA601: Bezlotoxumab for preventing recurrent Clostridium difficile infection (terminated appraisal)		✓		The formulary will reflect the TAG – CCG is the responsible commissioner.

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
TA602: Pomalidomide with bortezomib and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal)		✓		The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA603: Lenalidomide with bortezomib and dexamethasone for untreated multiple myeloma (terminated appraisal)		✓		The formulary will reflect the TAG – NHS England is the responsible commissioner.
7) Appeals against earlier decisions by the APC				
None				
8) Products considered by NTAG				
Andexanet alfa (Ondexxya®), Factor Xa inhibitor antidote.		✓		The formulary will reflect the NTAG position.
Patiromer (as patiromer sorbitex calcium) for the treatment of hyperkalaemia in adults.		✓		The formulary will reflect the NTAG position.
8) Miscellaneous decisions by the APC				
Chapter 11 & 13 of formulary	✓			Recommendations for changes to Chapter 11 and 13 to harmonise existing formularies into one APC formulary were approved.
Gender Dysphoria Section of the formulary (section 6.4.4)	✓ **A**			Agreed to list these drugs as Amber Specialist Initiation as per NHSE Primary Care Responsibilities in Prescribing & Monitoring Hormone Therapy for Transgender and Non-Binary Adults, and Children plus Adolescents for patients seen in NHS commissioned services. The position of prescribing in primary care following a private/online consultation for gender dysphoria is more contentious and raises issues on how GP should check provider to demonstrate that it has the necessary expertise before responding to the provider's request; and the extra workload this creates for a GP on individual by individual patient basis. It was agreed that APC does not support prescribing by GPs for patient following private/online consultation as per advice from BMA GP Committee.

DECISION SUMMARY

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	Approved	Refused	Deferred	
Paroxetine tablets	✓			Agree to add back into formulary as GREY drug for existing and patients moving into area from outside area

The following guidelines were presented to and approved at the November 2019 meeting of the APC:

- Stoma Accessories Guideline

The following guidelines were presented to and approved clinically at the November 2019 meeting of the APC for use in County Durham & Darlington but still require CCG financial approval:

- County Durham & Darlington Algorithm for Blood Glucose Lowering Therapy in Adults with Type 2 Diabetes

The following Green+ drug information leaflets were presented to and approved at the September 2019 meeting of the APC:

- Nil

The following shared care guidelines were presented to and approved at the September 2019 meeting of the APC:

- Nil

Other documents presented to and approved at the November 2019 meeting of the APC:

- County Durham and Tees Valley Formulary Application Form