County Durham and Darlington
Area Prescribing Committee

Summary of decisions made regarding new product requests considered at a meeting of the Committee on **Thursday 2nd November 2017**

Classification of products:

G **Green drug** - Can be initiated and prescribed in all care settings - Second line / alternative green drug

G+ **Green+ drug** Specialist initiation / recommendation. 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.

A **Amber 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				
Insulin Degludec 100 units/ml injection for paediatrics	✓ G+			Requested for use in paediatric type 1 diabetics. It may offer some advantages in that smaller dose required compared glargine or detemir, and can be given at any time of day giving greater dose flexibility. **Decision:** Request was approved
Glycopryonnium bromide 2mg/5ml oral solution for drooling in paediatrics (Sinalar®)			✓	Glycopyrronium bromide 2mg/5ml has been requested for the treatment of severe sialorrhoea in children and adolescents with chronic neurological disorders. Only licensed glycopyrronium oral solution in children and tablets are not licensed in children. More cost-effective than using unlicensed tablets. **Decision:** Deferred until has CDDFT CSTC approval.

DECISION SUMMARY

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
Ulipristal acetate 5mg tablets (Esyma®) (extension of license)	✓ A			License extension for intermittent use for up to 4 cycles in management of uterine fibroids. May delay progression to surgery. **Decision:** The request was approved for addition to the formulary as an AMBER drug for max 4 courses of 3 months duration each in the intermittent management of uterine fibroids. This is subject to an SCP being approved. Use outside of this considered a RED drug.
Ceftazidime / Avibactam 2g/0.5g injection (Zavicefta®)			✓	For use on consultant microbiologist advice within secondary only in multi-resistant infections with limited treatment options. **Decision:** Deferred until has CDDFT CSTC approval.
Ceftobiprole 500mg Injection			✓	For use on consultant microbiologist advice within secondary only in multi-resistant infections with limited treatment options. **Decision:** Deferred until has CDDFT CSTC approval.
3) New formulations & extensions to use				
None				
5) Products considered by NICE				
TA463 Cabozantinib for previously treated advanced renal cell carcinoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA464 Bisphosphonates for treating osteoporosis	✓ Oral = G IV = R			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA465 Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA466 Baricitinib for moderate to severe rheumatoid arthritis	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA467 Holoclar for treating limbal stem cell deficiency after eye burns	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner.

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TA468 Methylnaltrexone bromide for treating opioid-induced constipation (terminated appraisal)		✓		The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA469 Idelalisib with ofatumumab for treating chronic lymphocytic leukaemia (terminated appraisal)		✓		The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA470 Ofatumumab with chemotherapy for treating chronic lymphocytic leukaemia (terminated appraisal)		✓		The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA471 Eluxadoline for treating irritable bowel syndrome with diarrhea	✓ G+			The formulary will reflect the TAG – CCG is the responsible commissioner.
TA472 Obinutuzumab with bendamustine for treating follicular lymphoma refractory to rituximab	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA473 Cetuximab for treating recurrent or metastatic squamous cell cancer of the head and neck	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA474 Sorafenib for treating advanced hepatocellular carcinoma	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
TA475 Dimethyl fumarate for treating moderate to severe plaque psoriasis	✓ R			The formulary will reflect the TAG – CCG is the responsible commissioner.

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	Approved	Refused	Deferred	
TA476 Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic pancreatic cancer	✓ R			The formulary will reflect the TAG – NHS England is the responsible commissioner.
6) Northern (NHS) Treatment Advisory Group (N-TAG)				
Liraglutide (Saxenda®) for the treatment of obesity.		✓		The Northern (NHS) Treatment Advisory Group does not recommend the use of liraglutide (Saxenda®) for the treatment of obesity.
Paliperidone long acting injection (Xeplion®) and Paliperidone 3 monthly injection (Trevicta®) Janssen-Cilag for schizophrenia.	✓ A			The Northern (NHS) Treatment Advisory Group recommends the use of Paliperidone LAI and 3-monthly injection as per its licensed indications and as outlined in the updated Guidance on the Use of Antipsychotic Long-acting Injections in the North of England
7) Appeals against earlier decisions by the APC				
None				
8) Miscellaneous decisions by the APC				
Accrete D3® (calcium/vitamin D3) One a Day 1000 mg/880 IU Chewable Tablet		✓		New one tablet once a day dose. Current product is 1 tablet twice a day. **Decision:** Agreed not to add to formulary as an additional strength of Accrete D3 as may cause confusion with existing Accrete D3 and Adcal D3 being twice daily dosing.
Darbepoetin alfa (Aranesp®) injection **Epoetin alfa (Eprex®) injection** **Epoetin beta (NeoRecormon®) injection**	✓ R			Noted no SCP exists and RED on the Tees formulary **Decision:** Agreed to change from AMBER to RED as no SCP available and indications more suited to hospital only prescribing. This change will apply to new patients only and existing patients should be reviewed on an individual patient basis.
Gentamicin Nebulised	✓ R			Request to change from RED to AMBER. **Decision:** Agreed no change to current RAG status required as limited numbers of patients and there are currently supply issues with gentamicin. There is also a risk management issue as only specific preservative free brands can be given via nebulisation and this use of gentamicin is unlicensed.

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Alimemazine 10mg tablets and 7.5mg/5ml oral liquid	✓ R			High cost increase over past year and no greater efficacy than the other antihistamines. **Decision:** Agreed to change from GREEN to RED initially with a view to removal from formulary by March 2018 as still used in paediatric sedation protocol within CDDFT. This protocol is currently under review and the removal of alimemazine is being considered.
Xalatan®, Xalacom® and Azopt® eye drops				Currently being prescribed generically within primary care to ensure more cost-effective product is used. Secondary care have also been asked to follow this policy **Decision:** Agreed to list generically on the formulary.
Polyhexamethylene biguinide (PHMB) 0.02% Eye drops	✓ R			Included on NoT Gateshead formulary as RED drug for management of Acanthamoeba keratitis. **Decision:** Agreed to add to formulary as RED drug as per NoT Gateshead formulary for the management of Acanthamoeba keratitis.
Methenamine				**Decision:** Moved to Grey List as a Green+ drug as being recommended by urologists for recurrent UTI instead of Abx. Note only included in PHE guidance for use in non-pregnant women with recurrent UTI.
Sodium Valproate Tablets e/c - 200mg, 500mg, **Tablets MR - 200mg, 300mg, 500mg,** **Oral Solution - 200mg/5ml,** **Tablets (crushable) - 100mg**				RAG status review in light of recent safety warnings in women of child bearing potential. **Decision:** no change to current RAG status required as all prescribers been made of aware of safety warnings, and making a change to RAG status will not affect how safety messages are delivered during the time period a patient may be on the drug.
Valproic Acid Tablets E/C - 250mg, 500mg				RAG status review in light of recent safety warnings in women of child bearing potential. **Decision:** no change to current RAG status required as all prescribers been made of aware of safety warnings, and making a change to RAG status will not affect how safety messages are delivered during the time period a patient may be on the drug.

The following guidelines were presented to and approved at the November 2017 meeting of the APC:

- Nil

The following Green+ drug information leaflets were presented to and approved at the November 2017 meeting of the APC:

- Noqdirna (desmopression oral lyphilisate) – agreed to adopt Sunderland JFC document

The following shared care guidelines were presented to and approved at the November 2017 meeting of the APC:

- Apomorphine (CDDFT)

- Azathioprine (CDDFT)
- 6-Mercaptopurine (CDDFT)
- Ciclosporin (CDDFT)
- Hydroxychloroquine (CDDFT)
- Leflunomide (CDDFT)
- Mycophenolate (CDDFT)
- Sulfasalazine (CDDFT)