County Durham and Darlington Area Prescribing Committee

Thursday 2nd November 2017
11.30am – 2.30pm
Board Room, Appleton House

Present

Dr Ian Davidson, Director of Quality & Safety, North Durham CCG (Chair)
Gavin Mankin, RDTC Representative (Professional Secretary)
Dan Newsome, Medicines Optimisation Pharmacist, NECS
Kate Huddart Senior Pharmaceutical Advisor, DDES CCG
Chris Williams, Chief Pharmacist, TEWV FT
Jamie Harris, Chief Pharmacist, CD&DFT
Beverley Walton, Lead Clinical Pharmacist, CD&DFT
Joan Sutherland, Medicine Optimisation Lead Pharmacist, North Durham CCG
Mike Leonard , Directorate Pharmacist, TEWVFT
Chris Cunnington-Shore, Patient Representative
Brewis Henderson, Patient Representative
Dr Shafie Kamaruddin, Consultant, CD&D FT
Rob Pitt, LPC representative
Dr Catherine Harrison, GP Prescribing Lead, DDES CCG

In attendance

Angela Dixon, NECS - Professional secretary for Tees Medicines Management Group - observer

Andy Reay, NECS – item 4a

The meeting was quorate.

APC members and attendees were reminded to keep detailed discussions confidential to allow free and full debate to inform unencumbered decision making. Discretion should be used when discussing meetings with non-attendees and papers should not be shared without agreement of the chair or professional secretary, to ensure confidentiality is maintained.

Part 1 (11.30)

1a Apologies for absence:
Sarah McGeorge, Paul Walker, Neil Middleton, Claire Jones

1b Declarations of Interest

Declarations of interest:
The Chair reminded subgroup members of their obligation to declare any interest they may have on any issue arising at committee meetings which might conflict with the business of the APC.
Declarations declared by members of the APC are listed in the APC's Register of Interests. The Register is available either via the professional secretary or on the APC website at
http://medicines.necsu.nhs.uk/committees/durham-darlington-committees/

Declarations of interest from sub committees:
None declared

Declarations of interest from today's meeting:
Dr Shafie Kamaruddin declared interest in the insulin degludec application and item 3l as a Consultant Diabetologist. The group considered his clinical knowledge to be an advantage to the group when discussing these items and he was not asked to withdraw from the discussion. No direct financial interest was declared in the products themselves.

1c Minutes of the previous APC meeting held 7th September 2017
The minutes were accepted as a true and accurate record.

1d Matters Arising/Action Log

Actions from July 2017 meeting not on the agenda or action log
Nil

Action Log
Stopping Over-Medication in People with Learning Disabilities
Update from TEWV not due until March 2018.

TEWV Communications with GPs – update
Update from TEWV not due until March 2018.

CD&D DNP List – updated
Completed & on website. ITEM NOW CLOSED.

Lithium Shared Care Guidelines
Completed and on TEWV website with link from formulary & APC website. ITEM NOW CLOSED.

CD&D APC Terms of Reference – updated Sept 2017
Completed & on website. ITEM NOW CLOSED.

APC Meeting Day, Time & Venue for 2018
Venues booked for 2018 – see item 5m. ITEM NOW CLOSED.

Update to CD&D Drug Monitoring Document – Testosterone
Shared care guideline for testosterone still in development.

NHS England Gender Identity Consultation
Completed & submitted response to NHS England on behalf of the APC based on the discussion that had taken place at Sept 2017 APC. ITEM NOW CLOSED.

Managing prescribable items of low priority for NHS Funding – NHS England Consultation.
Completed & submitted response to NHS England on behalf of the APC based on the discussion that had taken place at Sept 2017 APC. ITEM NOW CLOSED.

Change to Local Gluten Free Policy – feedback received
Updated version of local CD&D policy approved via Chair's action. ITEM NOW CLOSED.

APC Letter re Managing Prescribing Costs
Completed and sent to stakeholders. Copy of letter also sent to CCG/CDDFT Financial Recovery Group. ITEM NOW CLOSED.

Adult Vitamin D – Quick Reference Guide
Completed & on website. ITEM NOW CLOSED.

Patient Decision Aids Resource – review
Completed & on website. ITEM NOW CLOSED.

Pain Guidelines
Completed and being currently being added to website. ITEM NOW CLOSED.

Erectile Dysfunction guideline
Still awaiting final version & summary of changes to policy from Nicole Theobald at NECS for adding to APC website.

Historic Actions
Subcutaneous methotrexate
Progress continues to be made around the homecare contract for subcutaneous methotrexate. A suitable template for GP computer systems is currently in development.

CDDFT Representatives to APC
Letter sent write to the CDDFT Medical Director in July 2017 to seek new consultant representatives to APC from CDDFT but no response as yet.
Discussion has taken place between the CDDFT Clinical Lead for Family Health to discuss increasing representation at APC. One issue that was raised was the timing of the meeting. By running from 11:30-2:30 it breaches 2 "sessions" for Consultants.
After discussion the APC agreed to change its meeting time to 9am-12noon from March 2018.

ACTION:
- **GM to re-arrange meeting venues from March 2018 to accommodate new meeting time.**
- **SK to continue to seek two more consultants to represent CDDFT at the APC.**

Osteoporosis Guideline
Draft still in progress and NECS await comments from CDDFT. May be delayed until early 2018.

Ciclosporin Eye Drops
No updated required until July 2018.

GP Information Leaflet for Desmopressin Lyophilisate from Sunderland JFC
Leaflet has now been produced and approved by Sunderland JFC. It was presented to the APC for adoption in CD&D. The APC agreed to adopt this leaflet.

ACTION:
- **GM to add GP Information Leaflet for Desmopressin Lyophilisate from Sunderland JFC to CD&D pages of NECS website.**

Accessing Palliative Medicines via the Urgent Care Centre
NECS are updating of the list of pharmacies which stock palliative care meds and their opening hours and this is still in progress. Information checked for Darlington and still awaiting information from County Durham. This is currently with provider management to take forward.

Concerns were raised around increasing prescribing of VSL#3 in primary care for non-pouchitis patients
Discussed with consultant concerned who has agreed to no longer prescribe for this indication due to lack of evidence/efficacy. ITEM NOW CLOSED.

Part 2 – Mental Health (12.00)

2a TEWV Drug & Therapeutics Committee Feedback – September 2017
CW presented to the APC a briefing report highlighting the main issues discussed at the recent

TEWV D&T.
The following issues were highlighted to the group:

- Valproate Patient Safety Alert – information circulation to all prescribers within TEWV.

2b Depression Medication Algorithm

A draft of the updated Depression Medication Algorithm for primary and secondary care was presented to the group for comment.

The APC approved the Depression Medication Algorithm subject to the following changes and final approval by TEWV D&T:

- Further information documents being incorporated in one single supporting document.
- Low dose venlafaxine in step 1 – add sentence to be considered only if responded to venlafaxine previously.
- Duloxetine in step 2 – consider changing RAG status from Green+ to Green to accommodate this.
- Include link at start of document to non-pharmacological option pathways.

ACTION:

- **CW to arrange for link to final approved version to be added to CD&D pages of NECS website once final approval received from TEWV D&T.**
- **CW to bring non-pharmacological option pathways to January 2018 APC for information and sharing with primary care as resource.**

2c Anxiety Medication Algorithm

A draft of an Anxiety Medication Algorithm for primary and secondary care was presented to the group for comment.

The APC approved the Anxiety Medication Algorithm subject to the following changes and final approval by TEWV D&T:

- Further information documents being incorporated in one single supporting document.
- Include link at start of document to non-pharmacological option pathways.

The APC noted that pregabalin is for secondary care initiation only in the management of anxiety which matches its GREEN+ formulary status for this indication.

ACTION:

- **CW to arrange for link to final approved version to be added to CD&D pages of NECS website once final approval received from TEWV D&T.**

2d Long Acting Antipsychotic Injections in Primary Care

The group discussed the letter from TEWV which recently went to N Durham CCG practices regarding the transfer of patients currently stable on Long Acting Antipsychotic Injections from secondary to primary care.
The group noted that this change in prescribing arrangement was unexpected and subsequently been put on hold pending a meeting of all stakeholders and commissioning managers.
The APC noted there was no action for it at this stage.

Part 3 – General (12.30)

3a Appeals against previous APC decisions

None received.

3b Update from Formulary Subgroup for November 2017 APC

This was presented to the group and the following actions were taken by the APC:

Formulary Updates since September 2017 APC for approval including RAG changes

Approved with suggested changes to RAG recommendation as follows:

NICE Topic Decision	Date Issued	Formulary status	Action taken following Oct 2017 FSG meeting
TA160 Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women (updated) This guidance has been partially updated by NICE's technology appraisal guidance on bisphosphonates for treating osteoporosis. NICE has withdrawn its guidance on the use of etidronate for the primary prevention of osteoporotic fragility fractures in postmenopausal women because etidronate is no longer marketed in the UK.	9.8.2017	Alendronate = Green Risedronate = Green alt Etidronate = not listed Raloxifene = Green+	Suggest no action required except to add link to formulary.
TA161 Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (updated) This guidance has been partially updated by NICE's technology appraisal guidance on bisphosphonates for treating osteoporosis. NICE has withdrawn its guidance on the use of etidronate for the secondary prevention of osteoporotic fragility fractures in postmenopausal women because etidronate is no longer marketed in the UK.	9.8.2017	Alendronate = Green Risedronate = Green alt Etidronate = not listed Raloxifene = Green+ Teriparatide = RED	Suggest no action required except to add link to formulary.
TA190 Pemetrexed for the maintenance treatment of non-small-cell lung cancer (updated) In August 2017, text at the start of the recommendations section stating that people who had had pemetrexed and cisplatin together as a first treatment could not have pemetrexed as maintenance treatment was removed. This was done following the publication of NICE's technology appraisal guidance on pemetrexed maintenance treatment for non-squamous non-small-cell lung cancer after pemetrexed and cisplatin.	10.8.2017	Listed as RED drug in 8.1.5	Suggest no action required except to add link to formulary.
T463 Cabozantinib for previously treated advanced renal cell carcinoma Cabozantinib is recommended, within its marketing authorisation, as an option for treating advanced renal cell carcinoma in adults after vascular endothelial growth factor (VEGF)-targeted therapy, only if the company provides cabozantinib with the discount agreed in the patient access scheme.	9.8.2017	Not listed in Chapter 8.1.5	Suggest add to formulary as a RED drug and include link.
TA464 Bisphosphonates for treating osteoporosis Oral bisphosphonates (alendronic acid, ibandronic acid and risedronate sodium) are recommended as options for treating osteoporosis in adults only if: • the person is eligible for risk assessment as defined in NICE's guideline on osteoporosis (recommendations 1.1 and 1.2) and • the 10‑year probability of osteoporotic fragility	9.8.2017	Oral = GREEN in in 6.2.2.2 IV = RED in 6.2.2.2	Suggest no action required except to add link to formulary.

fracture is at least 1%. Intravenous bisphosphonates (ibandronic acid and zoledronic acid) are recommended as options for treating osteoporosis in adults only if: • the person is eligible for risk assessment as defined in NICE's guideline on osteoporosis (recommendations 1.1 and 1.2) and • the 10‑year probability of osteoporotic fragility fracture is at least 10% or • the 10‑year probability of osteoporotic fragility fracture is at least 1% and the person has difficulty taking oral bisphosphonates (alendronic acid, ibandronic acid or risedronate sodium) or these drugs are contraindicated or not tolerated. The choice of treatment should be made on an individual basis after discussion between the responsible clinician and the patient, or their carers, about the advantages and disadvantages of the treatments available. If generic products are available, start treatment with the least expensive formulation, taking into account administration costs, the dose needed and the cost per dose.			
TA465 Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma Olaratumab, in combination with doxorubicin, is recommended for use within the Cancer Drugs Fund as an option for advanced soft tissue sarcoma in adults, only if: • they have not had any previous systemic chemotherapy for advanced soft tissue sarcoma • they cannot have curative treatment with surgery or their disease does not respond to radiotherapy • the conditions in the managed access agreement for olaratumab are followed.	9.8.2017	Not listed in 8.1.5	Suggest add as RED drug and add link to formulary.
TA466 Baricitinib for moderate to severe rheumatoid arthritis Baricitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs), only if: • disease is severe (a disease activity score [DAS28] of more than 5.1) and • the company provides baricitinib with the discount agreed in the patient access scheme. Baricitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to or who cannot have other DMARDs, including at least 1 biological DMARD, only if: disease is severe (a DAS28 of more than 5.1) and	9.8.2017	Not listed in 10.1.3	Suggest add as RED drug and add link to formulary.

• they cannot have rituximab and • the company provides baricitinib with the discount agreed in the patient access scheme. Baricitinib can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After an initial response within 6 months, withdraw treatment if at least a moderate EULAR response is not maintained.			
TA467 Holoclar for treating limbal stem cell deficiency after eye burns Holoclar (ex vivo expanded autologous human corneal epithelial cells containing stem cells) is recommended as an option in people with moderate to severe limbal stem cell deficiency after eye burns, only if: • it is only used to treat 1 eye and • people have already had a conjunctival limbal autograft or • there is not enough tissue for a conjunctival limbal autograft or it is contraindicated and • the company provides it with the discount agreed in the patient access scheme. • Moderate to severe limbal stem cell deficiency is defined by the presence of superficial corneal neovascularisation in at least 2 corneal quadrants, with central corneal involvement, and severely impaired visual acuity. Holoclar is recommended in people with moderate to severe limbal stem cell deficiency after eye burns for treating both eyes only: • in the context of research and • when there is not enough tissue for a conjunctival limbal autograft. Such research should be designed to generate robust evidence of the clinical- and cost-effectiveness of Holoclar in treating 2 eyes in people who do not have enough tissue for a conjunctival limbal autograft.	16.8.2017	Not listed in 11.8	Suggest add as RED drug and add link to formulary.
TA468 Methylnaltrexone bromide for treating opioid-induced constipation (terminated appraisal) NICE is unable to make a recommendation about the use in the NHS of methylnaltrexone bromide for treating opioid-induced constipation because no evidence submission was received from Swedish Orphan Biovitrum Ltd.	23.8.2017	Not listed	Suggest no action required.
TA469 Idelalisib with ofatumumab for treating chronic lymphocytic leukaemia (terminated appraisal) NICE is unable to make a recommendation about the use in the NHS of idelalisib with ofatumumab for	23.8.2017	Listed as RED drug in 8.1.5	Suggest no action required.

treating chronic lymphocytic leukaemia because no evidence submission was received from Gilead Sciences.			
TA470 Ofatumumab with chemotherapy for treating chronic lymphocytic leukaemia (terminated appraisal) NICE is unable to make a recommendation about the use in the NHS of ofatumumab with chemotherapy for treating chronic lymphocytic leukaemia because no evidence submission was received from Novartis Pharmaceuticals UK	23.8.2017	Listed as RED drug in 8.1.5	Suggest no action required.
TA471 Eluxadoline for treating irritable bowel syndrome with diarrhoea Eluxadoline is recommended as an option for treating irritable bowel syndrome with diarrhoea in adults, only if: • the condition has not responded to other pharmacological treatments (for example, antimotility agents, antispasmodics, tricyclic antidepressants) or • pharmacological treatments are contraindicated or not tolerated, and • it is started in secondary care. Stop eluxadoline at 4 weeks if there is inadequate relief of the symptoms of irritable bowel syndrome with diarrhoea.	30.8.2017	Listed as NOT APPROVED in 1.4.2 as per NTAG advice	Suggest change to GREEN+ drug and add link to formulary.
TA472 Obinutuzumab with bendamustine for treating follicular lymphoma refractory to rituximab Obinutuzumab in combination with bendamustine followed by obinutuzumab maintenance is recommended for use within the Cancer Drugs Fund as an option for treating adults with follicular lymphoma that did not respond or progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen, only if the conditions in the managed access agreement for obinutuzumab are followed.	30.8.2017	Listed as RED drug in 8.2.3	Suggest no action required except to add link to formulary.
TA473 Cetuximab for treating recurrent or metastatic squamous cell cancer of the head and neck Cetuximab in combination with platinum-based chemotherapy is recommended as an option for treating recurrent or metastatic squamous cell cancer of the head and neck in adults only: • if the cancer started in the oral cavity and • when the company provides the drug in line with the commercial access agreement with NHS England.	30.8.2017	Listed as RED drug in 8.1.5	Suggest no action required except to add link to formulary
TA474 Sorafenib for treating advanced hepatocellular carcinoma Sorafenib is recommended as an option for treating advanced hepatocellular carcinoma only for people with Child-Pugh grade A liver impairment, only if the company provides sorafenib within the agreed commercial access arrangement.	6.9.2017	Listed as RED drug in 8.1.5	Suggest no action required except to add link to formulary.
TA475 Dimethyl fumarate for treating moderate to severe plaque psoriasis Dimethyl fumarate is recommended as an option for treating plaque psoriasis in adults, only if the disease:	6.9.2017	Listed as RED drug in 13.5.2	Suggest no action required except to add link to formulary and to change listing from unlicensed product to licensed

• is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and • has not responded to other systemic therapies, including, ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet A radiation), or these options are contraindicated or not tolerated. 1Stop dimethyl fumarate treatment at 16 weeks if the psoriasis has not responded adequately. An adequate response is defined as: • a 75% reduction in the PASI score (PASI 75) from when treatment started or • a 50% reduction in the PASI score (PASI 50) and a 5‑point reduction in DLQI from when treatment started.			product.
TA476 Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic pancreatic cancer Paclitaxel as albumin-bound nanoparticles (nab‑paclitaxel) with gemcitabine is recommended as an option for untreated metastatic adenocarcinoma of the pancreas in adults, only if: • other combination chemotherapies are unsuitable and they would otherwise have gemcitabine monotherapy and • the company provides nab‑paclitaxel with the discount agreed in the patient access scheme.	6.9.2017	Listed as RED drug in 8.1.5	Suggest no action required except to add link to formulary.
NG72 Developmental follow-up of children and young people born preterm	30.8.2017	n/a	Suggest no action required as no specific drug recommendations.
CG160 Fever in under 5s: assessment and initial management (updated)	30.8.2017	n/a	Suggest no action required as changes to drug recommendations.
CG32 Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition (updated)	30.8.2017	n/a	Suggest no action required as no specific drug recommendations.
CG181 Advanced breast cancer: diagnosis and treatment	31.8.2017	all relevant drugs already on the formulary	Suggest no action required as all relevant drugs already on the formulary
CG153 Psoriasis: assessment and management **CG153 updated**	30.9.2017	all relevant drugs already on the formulary	Suggest no action required as all relevant drugs already on the formulary
CG156 Fertility problems: assessment and treatment (updated)	30.9.2017	all relevant drugs already on the formulary	Suggest no action required
CG160 Fever in under 5s: assessment and initial management (updated)	30.9.2017	n/a	Suggest no action required as no specific drug recommendations.
CG192 Antenatal and postnatal mental health: clinical management and service guidance (updated)	30.9.2017	all relevant drugs already	Suggest no action required

		on the formulary	
CG28 Depression in children and young people: identification and management (updated)	30.9.2017	all relevant drugs already on the formulary	Suggest no action required
CG54 Urinary tract infection in under 16s: diagnosis and management (updated)	30.9.2017	all relevant drugs already on the formulary	Suggest no action required
CG153 Psoriasis: assessment and management (updated)	30.9.2017	all relevant drugs already on the formulary	Suggest no action required
CG156 Fertility problems: assessment and treatment (updated)	30.9.2017	all relevant drugs already on the formulary	Suggest no action required
MHRA Drug safety advice	**Date Issued**	**Formulary status**	**Action taken following Oct 2017 FSG meeting**
Ibrutinib (Imbruvica▼): reports of ventricular tachyarrhythmia; risk of hepatitis B reactivation and of opportunistic infections Temporarily discontinue ibrutinib in patients who develop symptoms suggestive of ventricular arrhythmia and assess benefit-risk before restarting therapy.	Aug 2017	Listed as RED drug in 8.1.5	Suggest no action required except to add link to formulary.
Corticosteroids: rare risk of central serous chorioretinopathy with local as well as systemic administration Central serous chorioretinopathy is a retinal disorder that has been linked to the systemic use of corticosteroids.	Aug 2017	Listed as GREEN drugs in 6.3	Suggest no action required except to add link to formulary.
Adrenaline auto-injectors: updated advice after European review It is recommended that 2 adrenaline auto-injectors are prescribed, which patients should carry at all times.	Aug 2017	Listed as GREEN drug in 3.4.3.1	Suggest no action required except to add link to formulary.
Letters sent to healthcare professionals in July 2017 A summary of letters sent to healthcare professionals in July 2017 to inform of safety for: • Imbruvica▼(ibrutinib) and risk of hepatitis B reactivation: hepatitis B virus status to be established before initiating treatment • Zinbryta▼ (daclizumab): restrictions of use of in view of fatal fulminant liver failure • Aflibercept (Zaltrap▼) concentrate for solution for infusion 200 mg/8 mL: some batches contain previous Patient Information Leaflet; inform patients of warnings for heart failure • Valproate medicines: only for use when no other treatment is effective or tolerated in girls, women of childbearing potential, and women who are pregnant or planning pregnancy; important actions required — letter for specialists, specialist	Aug 2017	RED in 8.1.3 RED in 8.1.3 RED in 8.1.5 GREEN in 4 Not listed	Suggest no action required as full DSU issued and actioned previously. Suggest no action required as full DSU issued and actioned previously. Suggest no action required. Suggest no action required except to add link to formulary. Note the work done by NECS already.

nurses/midwives, and general practitioners and letter for pharmacists • Shortage of Trisenox (arsenic trioxide, 1 mg/ml concentrate for solution for infusion): replacement with imported arsenic trioxide injection 1 mg/ml (Phenasen) during supply shortage — prescribers should refer responsibilities for off-label or unlicensed use of medicines			Suggest no action required
Miconazole (Daktarin): over-the-counter oral gel contraindicated in patients taking warfarin Patients taking warfarin should not use over-the-counter miconazole oral gel (Daktarin).	Sep 2017	Listed as GREEN drug in 12.3.2	Suggest no action required except to add link to formulary.
Loperamide (Imodium): reports of serious cardiac adverse reactions with high doses of loperamide associated with abuse or misuse There have been reports of cardiac events including QT prolongation, torsades de pointes, and cardiac arrest in patients who have taken high or very high doses of loperamide as a drug of abuse or for self-treatment of opioid withdrawal.	Sep 2017	Listed as GREEN drug in 1.4.2	Suggest no action required except to add link to formulary.
Letters sent to healthcare professionals in August 2017 A summary of letters sent to healthcare professionals in August 2017 to inform of safety for: • INOmax (nitric oxide) cylinders: gas delivery might stop in the month of expiry when used with the Device INOmax DSIR • Decapeptyl SR (Triptorelin) 11.25 mg: change in salt	Sep 2017	Not listed Listed as GREEN+ drug in 4.5.1	Suggest no action required. Suggest add link to formulary.

NTAG recommendation	Date Issued	Formulary status	Action taken following Oct 2017 FSG meeting
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.	5.9.2017	Listed as NOT REVIEWED drug in 4.5.1	Suggest change to NOT APPROVED and add link to formulary.
Paliperidone long acting injection (Xeplion®) and Paliperidone 3 monthly injection (Trevicta®) Janssen-Cilag for schizophrenia. 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	5.9.2017	Listed as AMBER drug in 4.2.2	Suggest no action required except to add link to formulary as both preparations already included in the formulary.

Requested formulary amendments	Reasoning	BNF Chapter	Action taken following Oct 2017 FSG meeting
Addition of 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	9.6.4	Suggest not to add to formulary as an additional strength of Accrete D3 which is already on the formulary, AND may cause confusion with existing Accrete D3 and Adcal D3 being twice daily dosing.
Epoetin – change RAG status from AMBER to RED	No SCP exists and RED on the Tees formulary	9.1.3 a	Suggest 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 – change RAG status from RED to AMBER		5.1.4	Suggest no change 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.
Alimemazine – consider removing from formulary	High cost increase over past year and no greater efficacy than the other antihistamines	3.4.1	Suggest change from GREEN to RED initially 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 – list generically on formulary	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	11.6	Suggest list generically on the formulary.
Polyhexamethylene biguinide (PHMB) 0.02% Eye drops	Included on NoT Gateshead formulary as RED drug for management of Acanthamoeba keratitis.	11.3.1	Suggest add to formulary as RED drug.
Request for removal of a drug from the formulary	**Reasoning**	**BNF Chapter**	**Action taken following Oct 2017 FSG meeting**
Nil			

ACTION:

- **GM to update the online formulary with the approved changes once ratification received from Darlington/HAST CCG Joint Exec.**

3c CD&D Grey List – updated

The CD&D APC Grey List was due for review in November 2017. It has been reviewed by the FSG.

The following changes have been identified and were agreed by the APC:

- Methenamine – move 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.
- Pregabalin – update entry to match pain guidelines approved at Sept 2017 APC and to included approved mental health indications plus use in epilepsy.

ACTION:

- **GM to update the online formulary with the approved changes once ratification received from Darlington/HAST CCG Joint Exec.**
- **GM to arrange for final approved version to be added to CD&D pages of NECS website.**

3d RAG Status Review of Sodium Valproate

The APC reviewed the current RAG status of Sodium Valproate in light of recent safety updates regarding its use in pregnancy and women of child bearing potential.

Sodium valproate is currently has the following RAG ratings on the formulary:

- Epilepsy = Green
- Prophylaxis of migraine = Green (unlicensed indication but included in BNF)
- Mental health indications = Green+

The APC is asked to consider if still appropriate for GPs to start sodium valproate in women of child bearing potential without first referring to a specialist, and if the RAG status should stay the same or be changed to Green+ for all indications.

The FSG initially felt no change to the current GREEN status for epilepsy and prophylaxis of migraine, and GREEN+ for mental health use was required as all prescribers have been made aware of the warnings and the supporting risk management materials and where to find these. The APC agreed that no change to the RAG status of valproate was required as making changes to RAG status will make no change to how this safety message is delivered to the appropriate patient group at the appropriate time, and subsequently how the safety message is reinforced over time.

3e New Drug Applications

The following new formulary drug applications were discussed and approved by the APC:

New Drug Applications for Formulary	Reasoning	BNF Chapter	Action taken
Insulin Degludec for Paediatrics	Requested for use in 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.	6.1.1.2	Add to formulary as Green+ drug. Note already approved for use in adults
Ulipristal acetate 5mg tablets (Esyma®) (extension of license)	License extension for intermittent use for up to 4 cycles. May delay progression to surgery.	6.4.1.2	Add to formulary as AMBER drug for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age for up to 4 courses of 3 months each. If used for longer then considered a RED drug. Will only be added to formulary once SCG in place.

The following new formulary drug applications were deferred until they had full CDDFT CSTC approval:

New Drug Applications for Formulary	Reasoning	BNF Chapter
Glycopyrronium bromide (2mg/5ml) oral solution (Sialanar®) for drooling in paediatrics	Only licensed glycopyrronium oral solution in children and tablets are not licensed in children. More cost-effective than using	1.2

	tablets.	
Ceftazidime / Avibactam (Zavicefta®)	For use on consultant microbiologist advice within secondary only in multi-resistant infections with limited treatment options.	5.1.2 a)
Ceftobiprole	For use on consultant microbiologist advice within secondary only in multi-resistant infections with limited treatment options.	5.1.3 a)

ACTION:

- **GM to update the online formulary with the approved changes once ratification received from Darlington/HAST CCG Joint Exec.**

3f Shared Care Guidelines for Approval

Apomorphine

The existing apomorphine SCG has been reviewed by the Parkinson's disease team and put into the new APC SCG template. No major changes have been made to the content.
The APC approved this SCG subject to the following:

- GP Responsibilities – change "Re-referral back to specialist when appropriate" sub-heading to "Criteria for contacting specialist".

Azathioprine

The existing SCG was overdue for review. It has been updated to mirror the latest BSR, Dermatology and Gastroenterology guidelines for the monitoring and prescribing of DMARDs, and also put into the new APC SCG template. An accompanying letter to be used by specialists when requesting shared care with a GP for a DMARD has also been produced.
The APC approved this SCG subject to the following:

- Add in reference and link to BSR Guidelines on DMARDs in Pregnancy and Breast-Feeding.

The APC approved the accompanying request for shared care letter subject to the following:

- Change "The patient was commenced on this drug on …… and has been stable on the current dose for …. weeks" to "The patient was commenced on this drug on ……..and has been stable on the current dose since……"
- Change "The next blood monitoring is due on …….. and should be continued every …… weeks/months" to "The next blood monitoring is due on …… and should be continued in line with the shared care guideline."

6-Mercaptopurine

The existing SCG was overdue for review. It has been updated to mirror the latest Gastroenterology guidelines for the monitoring and prescribing of DMARDs, and also put into the new APC SCG template. An accompanying letter to be used by specialists when requesting shared care with a GP for a DMARD has also been produced.
The APC approved this SCG.
The APC approved the accompanying request for shared care letter subject to the following:

- Change "The patient was commenced on this drug on …… and has been stable on the current dose for …. weeks" to "The patient was commenced on this drug on ……..and has been stable on the current dose since……"
- Change "The next blood monitoring is due on …….. and should be continued every …… weeks/months" to "The next blood monitoring is due on …… and should be continued in line with the shared care guideline."

Ciclosporin

The existing SCG was overdue for review. It has been updated to mirror the latest BSR, Dermatology and Gastroenterology guidelines for the monitoring and prescribing of DMARDs,

and also put into the new APC SCG template. An accompanying letter to be used by specialists when requesting shared care with a GP for a DMARD has also been produced.
The APC approved this SCG subject to the following:

- Add in reference and link to BSR Guidelines on DMARDs in Pregnancy and Breast-Feeding.
- Add in line about branded prescribing to avoid inadvertent switching.
- Clarify in Adverse Events what is meant by "Significant rise in lipids".

The APC approved the accompanying request for shared care letter subject to the following:

- Change "The patient was commenced on this drug on …… and has been stable on the current dose for …. weeks" to "The patient was commenced on this drug on ……..and has been stable on the current dose since……"
- Change "The next blood monitoring is due on …….. and should be continued every …… weeks/months" to "The next blood monitoring is due on …… and should be continued in line with the shared care guideline."

Hydroxychloroquine

The existing SCG was overdue for review. It has been updated to mirror the latest BSR, Dermatology and Gastroenterology guidelines for the monitoring and prescribing of DMARDs, and also put into the new APC SCG template. An accompanying letter to be used by specialists when requesting shared care with a GP for a DMARD has also been produced.
The APC approved this SCG subject to the following:

- Add in reference and link to BSR Guidelines on DMARDs in Pregnancy and Breast-Feeding.

The APC approved the accompanying request for shared care letter subject to the following:

- Change "The patient was commenced on this drug on …… and has been stable on the current dose for …. weeks" to "The patient was commenced on this drug on ……..and has been stable on the current dose since……"
- Change "The next blood monitoring is due on …….. and should be continued every …… weeks/months" to "The next blood monitoring is due on …… and should be continued in line with the shared care guideline."
- Add in that patient has been informed of need to arrange 5 year eye check.

Leflunomide

The existing SCG was overdue for review. It has been updated to mirror the latest BSR, Dermatology and Gastroenterology guidelines for the monitoring and prescribing of DMARDs, and also put into the new APC SCG template. An accompanying letter to be used by specialists when requesting shared care with a GP for a DMARD has also been produced.
The APC approved this SCG subject to the following:

- Add in reference and link to BSR Guidelines on DMARDs in Pregnancy and Breast-Feeding.

The APC approved the accompanying request for shared care letter subject to the following:

- Change "The patient was commenced on this drug on …… and has been stable on the current dose for …. weeks" to "The patient was commenced on this drug on ……..and has been stable on the current dose since……"
- Change "The next blood monitoring is due on …….. and should be continued every …… weeks/months" to "The next blood monitoring is due on …… and should be continued in line with the shared care guideline."

Mycophenolate

The existing SCG was overdue for review. It has been updated to mirror the latest BSR, Dermatology and Gastroenterology guidelines for the monitoring and prescribing of DMARDs, and also put into the new APC SCG template. An accompanying letter to be used by specialists when requesting shared care with a GP for a DMARD has also been produced.
The APC approved this SCG subject to the following:

- Add in reference and link to BSR Guidelines on DMARDs in Pregnancy and Breast-Feeding.

The APC approved the accompanying request for shared care letter subject to the following:

- Change "The patient was commenced on this drug on …… and has been stable on the current dose for …. weeks" to "The patient was commenced on this drug on ……..and has been stable on the current dose since……"
- Change "The next blood monitoring is due on …….. and should be continued every …… weeks/months" to "The next blood monitoring is due on …… and should be continued in line with the shared care guideline."

Sulfasalazine

The existing SCG was overdue for review. It has been updated to mirror the latest BSR, Dermatology and Gastroenterology guidelines for the monitoring and prescribing of DMARDs, and also put into the new APC SCG template. An accompanying letter to be used by specialists when requesting shared care with a GP for a DMARD has also been produced.

The APC approved this SCG subject to the following:

- Add in reference and link to BSR Guidelines on DMARDs in Pregnancy and Breast-Feeding.

The APC approved the accompanying request for shared care letter subject to the following:

- Change "The patient was commenced on this drug on …… and has been stable on the current dose for …. weeks" to "The patient was commenced on this drug on ……..and has been stable on the current dose since……"
- Change "The next blood monitoring is due on …….. and should be continued every …… weeks/months" to "The next blood monitoring is due on …… and should be continued in line with the shared care guideline."

ACTION:

- **BW to make suggested changes to the SCPs and produce final approved version.**
- **GM to arrange for final approved versions to be added to CD&D pages of NECS website.**

3g NTAG Update

A verbal update on the NTAG recommendations following their September 2017 meeting was given.

- Liraglutide (Saxenda®) for the treatment of obesity.
- Paliperidone long acting injection (Xeplion®) and Paliperidone 3 monthly injection (Trevicta®) for schizophrenia

The formulary website will be updated accordingly.

ACTION:

- **GM to update the online formulary with the approved changes.**

3h CDDFT Unlicensed Medicines Policy

Shared with APC for information.

3i CDDFT Medicines Requiring Loading Doses Policy

Shared with APC for information.

3j RMOC Update

Commissioning Framework for Biological Medicines

Presented to APC for information. This has already been picked up by the APC High Cost Drugs Subgroup as part of its work.

Antimicrobial Resistance – Key Actions and Impact that can help the system during the winter period – October 2017

The APC discussed the need for it as a group to receive reassurance from its primary and

secondary stakeholders that work around tackling and managing antimicrobial resistance is occurring locally, and how performance locally is being monitored against national standards. The APC does not wish to duplicate work that is being done elsewhere.
After discussion it was agreed that needed to be cross sector overarching antimicrobrial group that submitted a report to the APC on a regular basis.

ACTION:

- **Antimicrobial resistance and performance locally against national targets to be an agenda item at the January 2018 APC.**

3k Update to CD&D Drug Monitoring Document

- **Theophylline**

Change still in progress and is awaiting input from respiratory team.

3l Freestyle Libre Glucose Monitoring Device

A verbal update was given to the APC for the current local position with regard to the commissioning status of the Freestyle Libre Glucose Monitoring Device.
This new device is available on the NHS as of 1st November 2017 and an RMOC Position Statement on its recommended use in England was issued also on the 1st November 2017.
The APC agreed on the need to issue guidance on its use within CD&D as soon as possible and was supportive of the recommendations on its use made in the RMOC Position Statement.
The APC was minded to the adopt the RMOC Position Statement on Freestyle Libre as it currently stands without further amendment as the CD&D recommendation for use of the device. The APC felt at this stage that Freestyle Libre should be treated as RED drug initially with initiation only by secondary care diabetologists to ensure it is used appropriately in the recommended patient populations. By retaining prescribing in secondary care, audit data would be more easily available to give assurance to APC of use within agreed place in therapy. The APC recognised the financial impact of retaining prescribing in secondary care and agreed to explore a mechanism for reimbursing the cost of prescribing within secondary care. Locally within CD&D the diabetologists have agreed to put in place the necessary audits as suggested by the RMOC to support the introduction of this new device and to ensure that patients are followed-up to check they continue to meet the criteria for its use.
It had been the plan that the RMOC statement would have been used by the Regional Value Based Commissioning Group to agree the NE&C policy but the next round of Value Based Commissioning is not due until April 2018, and there is an urgent need to for interim position to be approved.
After further discussion the APC agreed that although it supported the RMOC Position Statement they could not adopt the RMOC Position Statement within CD&D as yet until it knew what the interim NEC&C regional value based commissioning position was going to be. Whilst the APC was minded to adopt the RMOC Position Statement as its local prescribing policy for the use of Freestyle Libre this may change in light of any position adopted by the Regional Value Based Commissioning Group. The APC agreed therefore to urgently find out what the interim Regional Value Based Commissioning position was going to be and then agree the CD&D APC position in light of this via email or Chair's Action.

ACTION:

- **DN to find out what the NE&C Regional Value Based Commissioning Group position statement on the use of Freestyle Libre is.**
- **APC members to agree final CD&D APC policy on prescribing of Freestyle Libre via email/Chair's action once interim NE&C Regional Value Based Commissioning Group position is known.**

3m CD&D Formulary Subgroup Terms of Reference – Review

The Formulary Subgroup Terms of Reference were due for review in September 2017. They have been updated to include reference to the new Regional Medicines Optimisation Committees.
The review Terms of Reference were approved for a further 12 months.

ACTION:

- **GM to arrange for final approved version to be added to CD&D pages of NECS website.**

3n Lidocaine Patch Standard Refusal to Prescribe Letter – Darlington CCG

This letter has been developed by Darlington CCG to use when hospital specialists request that GPs continue the prescribing of lidocaine patches outside of agreed guidelines in effort to enforce the current formulary position.

The letter makes reference to the recently approved APC pain guidelines and formulary position of lidocaine patches.

The APC is asked for it's for views on this letter and if

a) it feels able to support its use.
b) APC feels a letter like this is good way of enforcing the formulary position & reduce inappropriate requests to primary care to prescribe lidocaine patches

Similar letters may also be produced for other drugs where their use does not follow guidelines/formulary position, and they have a high cost impact on drug budgets.

After discussion the APC agreed that this letter was not required because:

- System already in place using SIRMs to monitor non-formulary prescribing and then raise issues with clinicians as they arise.
- Language of letter may undermine relationships between primary and secondary care.
- Joint working has already achieved a reduction in appropriate use through the recent production of CD&D Pain Guidelines
- Concerns that could open floodgates for need to a letter for every individual drug on the DNP list.
- Letters regarding individual patients can only be signed by the patients GP not by the CCG Prescribing Lead.

Part 4 – Physical Health (13.30)

4a Regional policy regarding the treatment of Age-related Wet Macular Degeneration, based upon the prescribing of bevacizumab (Avastin®) as the first-line treatment option for patients newly diagnosed with wAMD

A briefing paper prepared by NECS on the development of a regional policy regarding the treatment of Age-related Wet Macular Degeneration and including the use of bevacizumab (Avastin®) was presented to the group for information. Discussions remain ongoing between commissioners and relevant provider organisation(s) around implementation of this policy particularly with regard to the legal position.

4b CD&D COPD Guidelines – proposed revision to match GOLD

The APC discussed and approved a request from the Respiratory Clinical Advisory Group to update the current APC guidelines for COPD to mirror GOLD recommendations rather than NICE. GOLD may offer some advantages over NICE in that it advocated a personalised treatment approach for each individual patient increasing and decreasing therapy as required based on the patient's current symptoms.

4c Bisphosphonates for Breast Cancer

The APC noted the latest recommendations from the Cancer Network with regard to bisphosphonates for the prevention of treatment associated osteoporosis and to reduce the risk of breast cancer recurrence in post-menopausal patients with early breast cancer.

The use of IV zoledronic acid will result in increased activity in secondary care. Zoledronic acid is in tariff; with the IV infusion tariff being picked up by the CCGs. CCGs will need to agree this increase in activity in contract discussions with the provider trusts.

ACTION:

- **APC stakeholders to highlight to commissioners and contract teams within their organisations this new treatment recommendation from the Cancer Network with regard to bisphosphonates for the prevention of treatment associated osteoporosis and to reduce the risk of breast cancer recurrence in post-menopausal patients with early breast cancer that will impact on current activity within secondary care, and the ask them to explore/agree the best model for delivering this treatment.**

Part 5 – Standing items (for information only)

5a Formulary Steering Group Minutes August 2017
For information.

5b TEWV D&T Minutes July 2017
For information.

5c CD&D FT Clinical Standards and Therapeutics Committee Minutes June & September 2017
For information.

5d CD&D D&T CAG August 2017 Minutes
For information. Note this group has now ceased to meet.

5e High Cost Drugs Group Minutes
Not yet available.

5f NTAG Minutes June 2017
For information.

5g NTAG Annual Report 2016/17
For information.

5h RDTC Horizon scanning – September & October 2017
For information.

5i MHRA Drug Safety Update – September & October 2017
For information.

5j NICE NG5 Medicines Optimisation Subgroup Minutes
No further meetings of the subgroup been held since June 2016.

5k AHSN Medicines Optimisation Steering Group Minutes – July 2017
For information.

5l Tees Medicines Governance Group Minutes – May 2017
For information.

5m APC Meeting Dates and Venues 2018
For information.

5n NHSE Specialised Commissioning Drugs Briefing – Autumn 2017
For information.

Chairman's Action

CD&D Gluten Free Guideline – updated

Updated version approved following discussion at September 2017 APC.

Any Other Business

Electronic Drug Kardex – Palliative Care

The group noted that work is ongoing with CDDFT to develop a suitable Electronic Drug Kardex – Palliative Care template for use within all GP computer systems across CD&D. GP practices are keen to move to an electronic kardex as soon as possible as it reduces transcription errors.

Date and time of next meeting:

Thursday 4th January 2018 11.30am – 2.30pm
Board Room, Appleton House, Durham