County Durham and Darlington Area Prescribing Committee

Thursday 7th September 2017
11.30am – 2.30pm
Board Room, North Durham CCG, Rivergreen, Akley Heads, Durham

Present

Dr James Carlton, Medical Advisor, DDES CCG (chair to item 3g)
Dr Ian Davidson, Director of Quality & Safety, North Durham CCG (chair from item 3g)
Dr Peter Forster, GP Prescribing Lead, DDES CCG (from item 3c)
Dr Esther Sheard, GP Prescribing Lead, North Durham CCG
Dr Martin Jones, GP Prescribing Lead, DDES CCG
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, Acting Deputy 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
Dr Shafie Kamaruddin, Consultant, CD&D FT
Claire Jones, Public Health Pharmacist, Durham County Council
Rob Pitt, LPC representative

In attendance

Dr Jane Leigh – GP Advisor, TEWVFT – items 2a-2c

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:
Brewis Henderson, Catherine Harrison, Paul Walker

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:
No declarations of interest relating to the agenda were raised.

1c Minutes of the previous APC meeting held 6th July 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
Valproate Patient Safety Alert
NECS have done some regional work around sodium valproate in pregnancy and women of child-bearing age, A resource pack has been produced and circulated which contains a briefing for practices/practice pharmacists, letters to patients, clinical system searches and patient/clinician agreements. This on Sept 2017 APC agenda for discussion. ITEM NOW CLOSED.

Contraceptives Section of Formulary
Formulary website updated accordingly. ITEM NOW CLOSED.

Shared Care Guidelines for Approval - Lithium (TEWV)
Comments from July APC included in final version approved by TEWV D&T July 2017 & brought to Sept 2017 APC for info. ITEM NOW CLOSED.

Shared Care Guidelines for Approval - Methylphenidate (TEWV)
Link added to formulary & TEWV website. Link still to be added to CD&D website. ITEM NOW CLOSED

Shared Care Guidelines for Approval - Atomoxetine (TEWV)
Link added to formulary & TEWV website. Link still to be added to CD&D website. ITEM NOW CLOSED

CDDFT Update June 2017
List of a list of original packs that CDDFT dispense which are issued just with an over-label bearing the patients name brought to September 2017 APC for information. ITEM NOW CLOSED.

Darlington/HAST CCG Exec Approval of APC Decisions
Confirmed NECS (Dan Newsome or Deborah Giles will be responsible using existing decision summary document. They will the communicate decision to RDTC.
Updated APC ToR on Sept 2017 APC agenda. ITEM NOW CLOSED.

Durham Guidelines for Transanal Irrigation
Completed & on website. ITEM NOW CLOSED

Nebulised Colomycin in Non-CF Patients – GP Information Leaflet
Completed & on website. ITEM NOW CLOSED

Letter Regarding Warfarin Prescribing
The consultant concerned has been spoken to re contents of letter and CDDFT are looking to appoint a lead clinician for anticoagulation. ITEM NOW CLOSED
NECS to review and update local atrial fibrillation guidelines.

Concerns raised around increasing prescribing of VSL#3 in primary care for non-pouchitis patients
Formulary application requested from Chronic Constipation Lead at CDDFT.

Historic Actions

Subcutaneous methotrexate

Progress continues to be made around the homecare contract for subcutaneous methotrexate with the homecare company recognising some of the issues/concerns that have been raised. The current pathway and shared care guideline for subcutaneous methotrexate is being updated and will include the need for an opt-in or opt-out response on an individual patient basis from the GP.

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.

Osteoporosis Guideline

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

Ciclosporin Eye Drops

No updated required until July 2018.

Analgesia Formulary Choices

On today's agenda. ITEM NOW CLOSED.

Stopping Over-Medication in People with Learning Disabilities

Data on potential number of patients has been collected. An audit/review template for use on GP systems is currently in development.

TEWV are looking for funding to employ a pharmacist to progress this work in addition to looking at how this has been progressed nationally.

TEWV agreed to provide an update in 6 months' time on progress with this workstream.

ACTION:

- **TEWV to provide an update in 6 months' time on progress with the Stopping Over-Medication in People with Learning Disabilities workstream**

TEWV Communications with GPs

On today's agenda.

GP Information Leaflet for Desmopressin Lyophilisate from Sunderland JFC

Still to be produced by Sunderland JFC.

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.

Letter for Clinicians across County Durham re Prescribing Savings

On today's agenda for approval. ITEM NOW CLOSED.

Part 2 – Mental Health (12.00)

2a TEWV Drug & Therapeutics Committee Feedback – July 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:

- Citalopram/Escitalopram – max dose and ECG guidance is currently under review.
- Hyperprolactinaemia guidance is currently under review.

The need to also review patients currently on citalopram 40mg daily and over 65 years old was also highlighted to the group.

2b TEWV GP Advisor
See Item 2c.

2c TEWV Communications with GPs – update
Dr Jane Leigh was in attendance to present an update on the TEWV Communications with GPs project.

A suite of letters is in development (incl discharge and review letters). There is current some problems with functionality and letters are not of the quality that would be hoped but the software supplier has been asked to resolve this.
Currently discharge letters are being sent via email. Eventually faxed requests should disappear and all team members including non-medical prescribers will be using the electronic letters to communicate with GPs.

An electronic GP referral process pilot has now been completed and the written evaluation is awaited. It is hoped to begin roll-out of this new electronic GP referral process shortly with CCGs and it is being supported by NECS. Templates for EMIS and SystemOne have been produced to support this.

Dr Leigh's team is developing some training, online training and masterclasses for primary care in different mental health therapeutic areas.

GPs were asked to raise any issues that arise with the team manager/consultant in the first instance, then the clinical director and finally Dr Leigh if still any concerns.

ACTION:
- **Dr Leigh to provide a 6 monthly update to TEWV D&T which will then be fed back to APC.**

Part 3 – General (12.30)

3a Appeals against previous APC decisions
None received.

3b Update from Formulary Subgroup for September 2017 APC
This was presented to the group and the following actions were taken by the APC:

Formulary Updates since July 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 Aug 2017 FSG meeting
TA446 Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma Brentuximab vedotin is recommended as an option for treating CD30‑positive Hodgkin lymphoma in adults, only if: • they have relapsed or refractory disease after autologous stem cell transplant and • the company provides brentuximab vedotin at the price agreed with NHS England in the	28.6.2017	Listed as RED drug in Chapter 8.1.5	Suggest no action required except to add link to formulary.

commercial access agreement. Brentuximab vedotin is recommended for use within the Cancer Drugs Fund as an option for treating CD30‑positive Hodgkin lymphoma in adults, only if: • they have relapsed or refractory disease after at least 2 previous therapies and • they cannot have autologous stem cell transplant or multi-agent chemotherapy and • the conditions of the managed access agreement are followed.			
TA447 Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer Pembrolizumab is recommended for use within the Cancer Drugs Fund as an option for untreated PD-L1-positive metastatic non-small-cell lung cancer in adults, only if: • their tumours express PD-L1 with at least a 50% tumour proportion score and have no epidermal growth factor receptor- or anaplastic lymphoma kinase-positive mutations • pembrolizumab is stopped at 2 years of uninterrupted treatment and no documented disease progression • the conditions in the managed access agreement for pembrolizumab are followed.	28.6.2017	Listed as RED drug in Chapter 8.1.5	Suggest no action required except to add link to formulary.
TA448 Etelcalcetide for treating secondary hyperparathyroidism Etelcalcetide is recommended as an option for treating secondary hyperparathyroidism in adults with chronic kidney disease on haemodialysis, only if: • treatment with a calcimimetic is indicated but cinacalcet is not suitable and • the company provides etelcalcetide with the discount agreed in the patient access schem	28.6.2017	Not listed in Chapter 8.3.4.3	Suggest add to formulary as a RED drug. Not listed as PBR excluded drug but expect to NHSE commissioned.
TA449 Everolimus and sunitinib for treating unresectable or metastatic neuroendocrine tumours in people with progressive disease Everolimus and sunitinib are recommended, within their marketing authorisations, as options for treating well- or moderately differentiated unresectable or metastatic neuroendocrine tumours (NETs) of pancreatic origin in adults with progressive disease. Everolimus is recommended, within its marketing authorisation, as an option for treating well-differentiated (grade 1 or grade 2) non-functional unresectable or metastatic NETs of gastrointestinal or lung origin in adults with progressive disease. Everolimus is recommended only when the company provides it with the discount agreed in the patient access scheme.	28.6.2017	Listed as RED drug in Chapter 8.1.5	Suggest no action required except to add link to formulary.

TA450 Blinatumomab for previously treated Philadelphia-chromosome-negative acute lymphoblastic leukaemia Blinatumomab is recommended within its marketing authorisation as an option for treating Philadelphia-chromosome-negative relapsed or refractory precursor B-cell acute lymphoblastic leukaemia in adults, only if the company provides it with the discount agreed in the patient access scheme.	28.6.2017	Not listed in Chapter 8.1.5	Suggest add to formulary as a RED drug and include link.
TA451 Ponatinib for treating chronic myeloid leukaemia and acute lymphoblastic leukaemia Ponatinib is recommended, within its marketing authorisation, as an option for treating chronic-, accelerated- or blast-phase chronic myeloid leukaemia in adults when: • the disease is resistant to dasatinib or nilotinib or • they cannot tolerate dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate or • the T315I gene mutation is present. Ponatinib is recommended, within its marketing authorisation, as an option for treating Philadelphia-chromosome-positive acute lymphoblastic leukaemia in adults when: • the disease is resistant to dasatinib or • they cannot tolerate dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate or • the T315I gene mutation is present. Ponatinib is recommended only if the company provides the drug with the discount agreed in the patient access scheme.	28.6.2017	Not listed in Chapter 8.1.5	Suggest add to formulary as a RED drug and include link.
TA452 Ibrutinib for untreated chronic lymphocytic leukaemia without a 17p deletion or TP53 mutation (terminated appraisal) NICE is unable to make a recommendation about the use in the NHS of ibrutinib for untreated chronic lymphocytic leukaemia without a 17p deletion or TP53 mutation because no evidence submission was received from Janssen–Cilag.	5.7.2017	Listed as RED drug in Chapter 8.1.5	Suggest no action required.
TA453 Bortezomib for treating multiple myeloma after second or subsequent relapse (terminated appraisal) NICE is unable to make a recommendation about the use in the NHS of bortezomib for treating multiple myeloma after second or subsequent relapse because no evidence submission was received from Janssen-Cilag.	5.7.2017	Listed as RED drug in Chapter 8.1.5	Suggest no action required.
TA454 Daratumumab with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma (terminated appraisal) NICE is unable to make a recommendation about the use in the NHS of daratumumab, with lenalidomide and dexamethasone, for treating relapsed or refractory multiple myeloma because no evidence submission was received from Janssen-Cilag.	5.7.2017	Not listed in Chapter 8.1.5	Suggest no action required.

TA455 Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people Adalimumab is recommended as an option for treating plaque psoriasis in children and young people aged 4 years or older, only if the disease: • is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and • has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contraindicated or not tolerated. Etanercept is recommended as an option for treating plaque psoriasis in children and young people aged 6 years or older, only if the disease: • is severe, as defined by a total PASI of 10 or more and • has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contraindicated or not tolerated. Ustekinumab is recommended as an option for treating plaque psoriasis in children and young people aged 12 years or older, only if the disease: • is severe, as defined by a total PASI of 10 or more • has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contraindicated or not tolerated.	12.7.2017	Listed as RED drugs in Chapter 13.5.3	Suggest no action required except to add link to formulary.
TA456 Ustekinumab for moderately to severely active Crohn's disease after previous treatment Ustekinumab is recommended, within its marketing authorisation, as an option for treating moderately to severely active Crohn's disease, that is, for adults who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF‑alpha inhibitor or have medical contraindications to such therapies. The choice of treatment between ustekinumab or another biological therapy should be made on an individual basis after discussion between the patient and their clinician about the advantages and disadvantages of the treatments available. If more than 1 treatment is suitable, the least expensive should be chosen (taking into account administration costs, dosage and price per dose). Ustekinumab should be given until treatment failure (including the need for surgery) or until 12 months after the start of treatment, whichever is shorter. People should then have their disease reassessed in accordance with NICE's recommendations for infliximab and adalimumab for the treatment of Crohn's disease to see whether treatment should continue.	12.7.2017	Not listed in Chapter 1.5.3	Suggest add to formulary as a RED drug and include link.

TA457 Carfilzomib for previously treated multiple myeloma Carfilzomib in combination with dexamethasone is recommended as an option for treating multiple myeloma in adults, only if: • they have had only 1 previous therapy, which did not include bortezomib and • the company provides carfilzomib with the discount agreed in the patient access scheme.	19.7.2017	Not listed in Chapter 8.1.5	Suggest add to formulary as a RED drug and include link.
T458 Trastuzumab emtansine for treating HER2-positive advanced breast cancer after trastuzumab and a taxane Trastuzumab emtansine is recommended, within its marketing authorisation, as an option for treating human epidermal growth factor receptor 2 (HER2)‑positive, unresectable, locally advanced or metastatic breast cancer in adults who previously received trastuzumab and a taxane, separately or in combination. Patients should have either received prior therapy for locally advanced or metastatic disease or developed disease recurrence during or within 6 months of completing adjuvant therapy. Trastuzumab emtansine is recommended only if the company provides it in line with the commercial access agreement with NHS England.	19.7.2017	Not listed in Chapter 8.1.5	Suggest add to formulary as a RED drug and include link.
TA459 Collagenase clostridium histolyticum for treating Dupuytren's contracture People who meet the inclusion criteria for the ongoing clinical trial (HTA-15/102/04), comparing collagenase clostridium histolyticum (CCH) with limited fasciectomy, are encouraged to participate in the study. For people not taking part in the ongoing clinical trial, CCH is recommended as an option for treating Dupuytren's contracture with a palpable cord in adults only if all of the following apply: • There is evidence of moderate disease (functional problems and metacarpophalangeal joint contracture of 30° to 60° and proximal interphalangeal joint contracture of less than 30° or first web contracture) plus up to 2 affected joints. • Percutaneous needle fasciotomy (PNF) is not considered appropriate, but limited fasciectomy is considered appropriate by the treating hand surgeon. • The choice of treatment (CCH or limited fasciectomy) is made on an individual basis after discussion between the responsible hand surgeon and the patient about the risks and benefits of the treatments available. • One injection is given per treatment session by a hand surgeon in an outpatient setting.	26.7.2017	Listed as RED drug in Chapter 10.3.1	Suggest add link to formulary and remove link to previous NTAG advice. Replaces NTAG advice from March 2012.
TA460 Adalimumab and dexamethasone for treating non-infectious uveitis Adalimumab is recommended as an option for treating non-infectious uveitis in the posterior segment of the	26.7.2017	Dexamethasone listed as RED drug in Chapter 11.8.2.4	Suggest no action required except to add link to formulary.

eye in adults with inadequate response to corticosteroids, only if there is: • active disease (that is, current inflammation in the eye) and • inadequate response or intolerance to immunosuppressants and • systemic disease or both eyes are affected (or 1 eye is affected if the second eye has poor visual acuity) and • worsening vision with a high risk of blindness (for example, risk of blindness that is similar to that seen in people with macular oedema). Stop adalimumab for non-infectious uveitis in the posterior segment of the eye in adults with inadequate response to corticosteroids if there is 1 of the following: • new active inflammatory chorioretinal or inflammatory retinal vascular lesions, or both or • a 2‑step increase in vitreous haze or anterior chamber cell grade or • worsening of best corrected visual acuity by 3 or more lines or 15 letters. Dexamethasone intravitreal implant is recommended as an option for treating non-infectious uveitis in the posterior segment of the eye in adults, only if there is: • active disease (that is, current inflammation in the eye) and • worsening vision with a risk of blindness.		Adalimumab not listed in Chapter 11.4.2	Suggest add to formulary as a RED drug and include link.
TA461 Roflumilast for treating chronic obstructive pulmonary disease Roflumilast, as an add-on to bronchodilator therapy, is recommended as an option for treating severe chronic obstructive pulmonary disease in adults with chronic bronchitis, only if: • the disease is severe, defined as a forced expiratory volume in 1 second (FEV1) after a bronchodilator of less than 50% of predicted normal, and • the person has had 2 or more exacerbations in the previous 12 months despite triple inhaled therapy with a long-acting muscarinic antagonist, a long-acting beta-2 agonist and an inhaled corticosteroid. Treatment with roflumilast should be started by a specialist in respiratory medicine.	26.7.2017	Listed as NOT APPROVED drug in Chapter 3.3.3	Suggest change to GREEN+ drug and include link. Also remove from DNP list as this advice replaces NICE TA224. Oral tablet. Roflumilast (Daxas▼): risk of suicidal behaviour – MHRA DSU 2013
TA462 Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma Nivolumab is recommended, within its marketing authorisation, as an option for treating relapsed or refractory classical Hodgkin lymphoma in adults after autologous stem cell transplant and treatment with brentuximab vedotin, when the company provides nivolumab with the discount agreed in the patient access	26.7.2017	Listed as RED drug in Chapter 8.2.4	Suggest no action required except to add link to formulary.

scheme.			
CG176 Head injury: assessment and early management (updated)	28.6.2017	n/a	Suggest no action required as no specific drug recommendations.
NG65 Spondyloarthritis in over 16s: diagnosis and management (updated) In June 2017, we updated recommendation 1.2.7 to clarify the advice on what imaging should be done.	28.6.2017	n/a	Suggest no action required as no specific drug recommendations changed.
CG99 Constipation in children and young people: diagnosis and management (updated)	26.7.2017	n/a	Suggest no action required as no specific drug recommendations changed.
NG71 Parkinson's disease in adults	26.7.2017	All relevant drugs included in formulary	Suggest no action required except to add link to start of chapter 4.
MHRA Drug safety advice	**Date Issued**	**Formulary status**	**Action taken following Aug 2017 FSG meeting**
Denosumab (Prolia, Xgeva▼): reports of osteonecrosis of the external auditory canal Denosumab is associated with a risk of osteonecrosis of the jaw, osteonecrosis of the external auditory canal has also been reported with denosumab.	June 2017	Listed as GREEN+ in Chapter 6.6.2.2	Suggest no action required except to add link to formulary.
Brimonidine gel (Mirvaso): risk of systemic cardiovascular effects; not to be applied to damaged skin Systemic cardiovascular effects including bradycardia, hypotension, and dizziness have been reported after application.	June 2017	Listed as NOT APPROVED in Chapter 13.6.3	Suggest no action required except to add link to formulary.
Pseudoephedrine and ephedrine: regular review of minimising risk of misuse in the UK Sales restrictions introduced in 2008 continue to be successful in managing the risk of misuse of pseudoephedrine and ephedrine.	June 2017	Listed as GREEN in Chapter 3.10	Suggest no action required.
e-cigarettes and refill containers (e-liquids): report suspected side effects and safety concerns Use the Yellow Card Reporting Scheme to support the safety of e-cigarettes and refill containers (e-liquids).	June 2017	Not listed	Suggest no action required.
Letters sent to healthcare professionals in May 2017 A summary of letters sent to healthcare professionals in May 2017 to inform of safety for: • Pharmalgen (Bee Venom and Wasp Venom) Initial kits: implementation of serial dilution protocol for up-dosing; risk of dosing errors (see dilution chart) • Bendamustine (Levact): increased mortality observed when used in non-approved combination treatments or outside approved indications • ERWINASE: notice of special handling instructions—vials of ERWINASE from batch 182G should be used with a 5-micron filter needle	June 2017	Not listed RED drug in Chapter 8.1.1 Not listed	Suggest no action required.
Daclizumab (Zinbryta▼) and risk of severe liver injury: initiation in multiple sclerosis now restricted, promptly review patients already on treatment While an urgent EU-wide review of new information on liver safety is under way, promptly review patients on treatment.	July 2017	Listed as RED drug in Chapter 8.2.4	Suggest no action required except to add link to formulary.

Bendamustine (Levact): increased mortality observed in recent clinical studies in off-label use; monitor for opportunistic infections, hepatitis B reactivation Recent clinical trials have shown increased mortality when bendamustine (Levact) was used in combination treatments outside its approved indications.	July 2017	Listed as RED drug in Chapter 8.1.1	Suggest no action required except to add link to formulary.
Nivolumab (Opdivo▼), pembrolizumab (Keytruda▼): reports of organ transplant rejection **There have been reports of rejection of solid organ transplants in patients treated with nivolumab or pembrolizumab.**	July 2017	Nivolumab = RED drug in Chapter 8.2.4 Pembrolizumab = RED drug in Chapter 8.1.5	Suggest no action required except to add link to formulary.
Letters sent to healthcare professionals in June 2017 A summary of letters sent to healthcare professionals in June 2017 to inform of safety for: • Arsenic Trioxide (Trisenox) 1 mg/mL concentrate for solution for infusion: importation and over-labelling of United States (US) Trisenox stock as Teva UK interim supply • Uptravi▼ (selexipag): concomitant use with strong CYP2C8 inhibitors (eg, gemfibrozil) now contraindicated • Cinryze▼ (C1 esterase inhibitor [human]): recommendations to prescribers in view of a potential supply shortage • DepoCyte (cytarabine): follow-up on EU supply issue • Clexane (enoxaparin sodium): updates to strength expression, dose regimens in DVT/PE, use in patients with severe renal impairment	July 2017	Not listed Not listed RED drug in chapter 3.4.3.2 RED drug in chapter 8.1.3 GREEN drug in Chapter 2.8.1	Suggest no action required. Suggest no action required. Add link to formulary. Suggest no action required. Add link to formulary.
NTAG recommendation	**Date Issued**	**Formulary status**	**Action taken following Aug 2017 FSG meeting**
Rituximab Biosimilars The Northern (NHS) Treatment Advisory Group considered an appraisal of Rituximab Biosimilars for Rheumatoid arthritis (RA) in adult patients and recommends the use of rituximab biosimilars as an option for use in adults where the originator product (MabThera®) would normally be prescribed.	June 2017	Listed as RED drug in Chapter 10.1.3	Suggest add Rituximab Biosimilars brand names and strengths to formulary PLUS add link to NTAG advice.
Sodium oxybate (Xyrem®) in the management of narcolepsy with cataplexy in adult patients The Northern (NHS) Treatment Advisory Group only recommends the use of sodium oxybate in adult patients who have received and benefited from treatment with sodium oxybate as commissioned by NHS England. i.e. continuing treatment for those >19 years old. The strict NHS England criteria for starting and stopping must continue to be followed. The use of sodium oxybate in new adult patients is not recommended. NETAG reviewed sodium oxybate in 2009 and did not recommend use, since it was considered unlikely to be cost effective. There is limited new evidence since that time.	June 2017	Listed as NOT APPROVED in Chapter 4.1.1	Suggest change to RED drug for use in both children and as per NTAG advice.
Pitolisant (Wakix®) for the treatment of narcolepsy with or without cataplexy in adults. The Northern (NHS) Treatment Advisory Group does not recommend the use of Pitolisant.	June 2017	Not listed in Chapter 4.1.1	Suggest add to formulary as NOT APPROVED drug PLUS add link to NTAG advice.
Qutenza® (capsaicin) cutaneous patch for neuropathic pain (updated)		Listed as NOT APPROVED in	Suggest add to formulary as RED drug add link to

The Northern (NHS) Treatment Advisory Group considered an appraisal of the use of Qutenza® (capsaicin) patches for neuropathic pain and recommends use of Qutenza® as a fourth line agent for neuropathic pain and in line with the regionally agreed pathway.		Chapter 4.7.3	NTAG advice. This patch will need to be administered by a specialist and under a local anaesthetic to reduce potential application related discomfort patients will be keen to ensure that it is of benefit.
Requested formulary amendments	**Reasoning**	**BNF Chapter**	**Action taken following Aug 2017 FSG meeting**
Atorvastatin 10mg and 20mg chewable tablets	More cost effective than simvastatin or atorvastatin liquid.	21.12	Suggest add to formulary as Green alternative drug for use in patients with swallowing difficulties needed a statin. To include note to be used instead of simvastatin or atorvastatin oral suspension
Benperidol 0.25mg tablets	Only licensed preparation for For the control of deviant anti-social sexual behaviour	4.2.1	Suggest add to formulary as GREEN + as per TEWV Safe Transfer of Prescribing document
Fluphenazine Decanoate (Modecate®) Injection	Being discontinued from 2018	4.2.2	Add note that no new patients to be started on it as being discontinued from 2018.
Enoxaparin Injection	Now labelled in units and mg	2.8.1	Add strength in units and mg to formulary.
New Drug Applications for Formulary	**Reasoning**	**BNF Chapter**	**Action taken following Aug 2017 FSG meeting**
None			
Request for removal of a drug from the formulary	**Reasoning**	**BNF Chapter**	**Action taken following Aug 2017 FSG meeting**
Phenindione 50mg tablets	Strength discontinued by manufacturer	2.8.2	Suggest remove 50mg strength from formulary.

ACTION:

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

3c CD&D DNP List – updated

The current CD&D Do Not Prescribe List is now due for review.
It has been reviewed by the FSG against the proposed list of items which should not routinely be prescribed in primary care from NHS England.
The following changes have been identified and were agreed by the APC:

- Promazine – no change as BNF still lists as less suitable for prescribing
- 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.
- Roflumilast – now NICE TA approved July 2017 – suggest remove
- Apremilast for psoriasis now NICE TA – suggest remove
- Meningitis – clarify it is the ACWY vaccine that is not prescribable on the NHS for travel purposes.
- Trimipramine – add as included on NHSE list and not a cost-effective use of resources.

It was also agreed that the Combined Hep A/Hep B vaccine be added to DNP list as Hep B not prescribable on the NHS for travel purposes. This is already the case in Darlington CCG. The APC noted the current supply shortages with Hep B vaccine and that Public Health England have issued guidance to mitigate the shortages and the combined vaccine is recommended in certain circumstances to help manage the shortages currently. Prescribers are advised to follow Public Health England until supply issues are resolved.

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 New Drug Applications
None received for this meeting.

3e Shared Care Guidelines for Approval
Lithium (TEWV)
A final version of the updated lithium shared care guideline was presented to the group for endorsement. The group noted that all the changes suggested at the July 2017 APC had been incorporated and the guideline had now been approved by the TEWV D&T.

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

3f NTAG Update
A verbal update on the NTAG recommendations following their June 2017 meeting was given.

- Rituximab Biosimilars
- Sodium oxybate (Xyrem®) in the management of narcolepsy with cataplexy in adult patients.
- Pitolisant (Wakix®) for the treatment of narcolepsy with or without cataplexy in adults.
- Qutenza® (capsaicin) cutaneous patch for neuropathic pain

The formulary website will be updated accordingly.

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

3g CD&D APC Terms of Reference – updated Sept 2017
The APC Terms of Reference have been updated to clarify accountability arrangements, decision making process, decision making powers, appeals process and how NICE TA approved drugs are included in the formulary.
The changes were approved by the APC.

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

3h APC Meeting Day, Time & Venue for 2018

The group discussed the possibility of changing its meeting day and time. After discussion the group agreed to stick with the current meeting time and meeting on the first Thursday of alternate months but to alternate the meeting venue between the north and south of the APC area where possible.

ACTION:

- **GM to arrange meeting venues for 2018 alternating between Durham and Darlington West Park/Sedgefield Community Hospital where possible.**

3i CDDFT Overlabelled Original Packs

The CDDFT list of original packs that they dispense which are issued just with an over-label bearing the patient's name was shared with the APC for information. This will help address some of administration/prescribing issues that have arisen in care homes following the discharge of patients from CDDFT with such medicines.

3j Update to CD&D Drug Monitoring Document

- **Testosterone**

After discussion with CDDFT endocrinologists and GPs it was agreed that a shared care agreement was required for testosterone due to the variable approach to monitoring in primary care and that patients tend not to be discharge from specialists.

- **Theophylline**

Change still in progress and is awaiting input from respiratory team

ACTION:

- **SK to develop a shared care guideline for testosterone.**

3k NHS England Gender Identity Consultation

The group discussed and agreed a response to the current NHS England Gender Identity Consultation, specifically to the questions around prescribing arrangements for hormone therapy. The group agreed that Option C was the best option from the perspective of primary care and that the one that GPs locally would be most comfortable with.

ACTION:

- **GM to submit a response on behalf of the APC based on the discussion that had taken place.**
-

3l Managing prescribable items of low priority for NHS Funding – NHS England Consultation

The group discussed and agreed a response to the current NHS England Consultation on Items Which Should not be Routinely Prescribed in Primary Care.

The group agreed that the current list of proposed products was appropriate and that the majority of these were already on the local DNP list.

The following comments were made in the discussions:

- Would be easier to implement in if many of these drugs were added to the Drug Tariff Black List
- Work should be done nationally by NHSE to target those CCGs specifically which have the highest spend on each of these drugs. This is because many CCGs have already done a lot of good work to reduce their prescribing of these drugs.
- With regard to OTC medicines their future inclusion should follow on from work that has been and is being done by the NE Prescribing Forum so there are no areas of grey. It was also suggested the Drug Tariff Black List needs to be revamped to ensure all brands of the relevant OTC medicines are included e.g. cough medicines.
- The discussion amongst the public that promotion of this workstream in the media has

generated has been useful in patients appreciating the need to manage NHS resources.

The group agreed to include in the response that "NHS England should issue clear, national advice on how changes should be made and how to transition to alternative products. This will enable clear advice to be followed in primary care, reducing the need for secondary care involvement. It is unclear what is meant by a "cooperation arrangement". There is a risk that prescribing will be transferred to secondary care unnecessarily and as such the clear guidance mentioned previously should articulate the relevant clinical strategies. This should be done once at a national level to provide clear support to this change."

ACTION:

- **GM to submit a response on behalf of the APC based on the discussion that had taken place.**

3m Change to Local Gluten Free Policy – feedback received

The group discussed some feedback that has been from patients within DDES CGG around the recent changes to the local gluten free prescribing policy. Many feel that the new guidance is not clear on what is and what is not allowed when it comes to "bread" e.g. are bread rolls, baguettes, ciabattas allowed.
The APC felt that a standard approach was required across the NE&C to avoid any ambiguity and to ensure consistency in what is a regional policy.

ACTION:

- **To feedback to Helen Seymour the comments that have been received on what is allowed to be prescribed (e.g. what is meant by "bread") so that is can be clarified and standardised across the region.**

3n Regional Resource Pack – Sodium Valproate in Pregnancy & Women of Child-Bearing Age

NECS have done some regional work around sodium valproate in pregnancy and women of child-bearing age, A resource pack has been produced and circulated which contains a briefing for practices/practice pharmacists, letters to patients, clinical system searches and patient/clinician agreements. This resource pack was shared with the APC for information and the group noted that practice pharmacists are beginning to review the patients that have been identified.

3o APC Letter re Managing Prescribing Costs

At the May 2017 APC the group discussed a request from the CCG/CDDFT Financial Recovery Group to write a letter to all clinicians across County Durham with a reminder about ensuring cost effective prescribing to continue to support the management of NHS resources locally. After discussion the group felt to was important to highlight to the CCG/CDDFT Financial Recovery Group all the work that had already been done to date to ensure cost-effective prescribing and efficient use if NHS resources locally. It was felt that any letter to clinicians should thank them for their efforts to date and highlight that the CD&D Medicines Optimisation agenda had already helped to manage prescribing costs, and these efforts should be maintained. A draft of this letter is now presented to the APC for approval.

The letter was approved by the group subject to the last sentence being changed to read "Please continue this excellent prescribing practice in these ongoing challenging times."

ACTION:

- **GM to update letter and circulate to stakeholder organisations for onward dissemination to their prescribers.**
- **KH to send a copy of the letter to the CCG/CDDFT Financial Recovery Group**

Part 4 – Physical Health (13.30)

4a Adult Vitamin D – Quick Reference Guideline

The group discussed and approved an Adult Vitamin D – Quick Reference Guideline that has been produced for primary care in CD&D subject to the following minor change:

- Costs to be expressed as monthly.

It was also agreed that the choice of which product to use between Fultium D3 and Plenachol should be left to individual clinician choice. It was felt appropriate to have two product options available and currently most prescribers were most familiar with the Fultium D3 product range.

ACTION:

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

4b Patient Decision Aids Resource – review

An updated version of the CD&D APC Patient Decision Aids Resource was presented to and approved by the group.

ACTION:

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

4c Patient Safety – Quinolones and Tendon Damage

A briefing reminding prescribers around the potential for quinolones and tendon damage was circulated to the group for information.

4d Neuropathic Pain Guideline

The final documents around pain management produced by the Task & Finish Group were presented to the group for approval. The documents are:

1. Opioid Prescribing for Persistent (Non-Cancer) Pain in Adults
2. Key Messages: For Pain Management Scenarios
3. Pharmacological Treatment of Neuropathic Pain

APC are requested to consider the following amendments (blue and underlined) which were received after the final drafts were circulated:

Document 1: Opioid Prescribing for Persistent (Non-Cancer) Pain in Adults

Page 4 (additions)

2. The dose of opiates in these situations should be under 100mg per day equivalent of morphine sulfate (see appendix for opioid equivalence) and opiates are more effective if used intermittently (not in palliative care). – change approved by APC

4. If 100mg of morphine sulfate equivalent is not effective then it should be discontinued through tapered reduction, even if there are no other therapeutic options left as it is likely to do harm without any benefit. – change approved by APC.

Page 5 (amendment)

3. If 20mg (as a bolus or total daily dose? If bolus: this has risks of respiratory depression and shall induce nausea in opioid naive patient; If daily dose: this is less than 240mg DHC or 400mg Tramadol) of short acting morphine sulfate is not effective it is unlikely that opiates will have any long term beneficial effects. (pain team normally use a trial of slow release morphine twice daily starting at 10mg twice daily increasing

by 10mg per day each week titrating up to improved function / side effects or 30mg twice daily which takes 5-6 weeks and reduce by reversing this process. eg Zomorph 10mg x2; x3; 20mg x 2; then 20,10,20; then 30mg x2 as takes 5 days to reach steady state and low slow regime induces fewer side effects. – APC approved change to trial of Zomorph 10mg BD and amend 20mg to single acute dose of 20mg.

Document 2: Key Messages: For Pain Management Scenarios

Page 3 (additions)

1. Ongoing pain is often due to changes in the processing of pain information rather than a symptom of an underlying pathology. Clinical Assessment and explanation of the diagnosis to the patient is part of the therapy. This should include assessment of function (what does pain stop) and identification of yellow flags. People with persistent pain often have 3 or more pains. – APC approved addition of "Clinical Assessment and explanation of the diagnosis to the patient is part of the therapy" .

2. Red flags (Biological harm indicators) and Orange flags (Psychiatric harm issues) MUST be excluded before any treatment commenced. – not approved by APC as this a summary document.

7. The education programmes for patients and graded exercise on referral schemes may be useful to help patients to self-manage – not approved by APC as no graded exercise scheme exists.

8. Being active is very important; the less active a patient is, the more painful it is to move and patient may become more fearful, and a vicious cycle ensues. – not approved by APC as implied in "vicious cycle".

9. Realistic Goal setting, pacing and planning are useful strategies for managing a pain problem – change approved by APC.

10. It is OK to say that nothing more can be given to the patient in terms of medical treatment. It may not be helpful to give the patient false hope with further treatments and referrals, looking for an elusive cure. However, continued support addressing yellow flags with self-management strategies is essential. – change not approved by APC as inclusion of yellow flags not helpful in this summary document.

Page 4 (deletion and additions)

9. Consider referral to a physiotherapist or occupational therapist who can offer individualised management ~~that may include manual therapy~~, which can be beneficial. *(frequent manual therapy runs counter to self-management as it promotes active treatment and passive patient* – APC approved addition of "occupational therapist".

10. Promote self-~~efficiency~~ efficacy behaviours and quality of life by encouraging patients to explore and maintain meaningful activities and interests through goal setting and activity planning. – APC suggest and approved change to "self-sufficient behaviours".

Page 5 (additions)

1. Neuropathic pain is caused by dysfunctional, damaged or injured nerves sending incorrect signals to the brain. It can have a metabolic, infective, traumatic, toxic (eg post chemotherapy), inflammatory/autoimmune, vascular, malignancy or musculoskeletal cause. – change not approved by APC as minor point.

2. The pain can be spontaneous, or evoked. Continuous or intermittent, superficial ~~or evoked~~. It can be made worse by temperature change or gentle touch. – change approved by APC.

Page 6 (addition and amendment)

3. Complete pain relief is rarely achieved; the goal of therapy should be to improve physical, social and emotional functioning, pain reduction is secondary. ~~to reduce symptoms enough to support improvement in physical, social and emotional functioning.~~ . – change not approved by APC as original sentence is fine.

5. ~~Patients must be made aware of the long-term effects of opioids on the endocrine and immune systems. Further information on opioids for patients is available here~~. The patient should be advised not to drive at the start of therapy, and when doses are increased. They should only then drive if they feel fit to do so. It is their responsibility to inform the DVLA that they are taking such medications (see Department for Transport Guidance). Patients must be made aware of the long-term effects of opioids on the endocrine and immune systems. Further information on opioids for patients is available here. – change not approved by APC as original sentence is fine.

Page 7 (additions)

1. Review

Patients on opioids should be regularly reviewed to determine whether opioids are meeting treatment goals (improving function) and whether opioids can be reduced to lower dosage or discontinued to. – change not approved by APC as original sentence is fine.

2. To taper?

Consider tapering to a reduced opioid dosage or tapering and discontinuing opioid therapy when your patient:

- Requests dosage reduction
- Does not have clinically meaningful improvement in pain and function
- Is on dosages greater or equal to 100mg morphine sulphate or equivalent /day without benefit
- Shows signs of substance use disorder (e.g. work or family problems related to opioid use, difficulty controlling use)
- Experiences overdose or other serious adverse event
- Shows early warning signs for overdose risk such as confusion, sedation, or slurred speech
- Develops other pathologies eg renal, OSAS, depression, or has increasing

polypharmacy – change approved by APC subject to OSAS being defined.

5. Discuss

The increased risk for accidental overdose if patients quickly return to a previously prescribed higher dose. – change approved by APC.

Document 3: Pharmacological Treatment of Neuropathic Pain

Page 14 (addition)

Cost
Tramadol 50mg capsules - eight daily for seven days treatment £1.61 (RDTC Jan 2017) (£83 per year) – change approved by APC.

Page 18 (addition)

Consider prescribing lidocaine plasters. **This is the only licensed indication for lidocaine patches, and the only situation indicated by this advisory group (for initiation in General Practice (*the pain consultants use it in some other neuropathic pain conditions and to help tapering down opioids)*.** They have a better side effect profile than oral medication, particularly in the elderly or in those where central nervous system side effects are a concern. – change not approved by APC as lack of published clinical evidence to support use of lidocaine patches for unlicensed indications, unlicensed use is non-formulary, and unlicensed use of lidocaine patches is not supported by NHSE "Items which should not be routinely be prescribed in primary care".

Page 19 (addition)

Additional information
The off license use of lidocaine plasters has been a significant prescribing cost burden both locally and nationally, prescribers are asked to review efficacy and indication regularly. The position of the guideline development group is that lidocaine patches are not to be used outside their licensed indications (without specific advice from pain specialists). – change not approved by APC as lack of published clinical evidence to support use of lidocaine patches for unlicensed indications, unlicensed use is non-formulary, and unlicensed use of lidocaine patches is not supported by NHSE "Items which should not be routinely be prescribed in primary care".

The three documents were approved subject to the APC agreed amendments.

ACTION:

- **JS to update Opioid Prescribing for Persistent (Non-Cancer) Pain in Adults, Key Messages: For Pain Management Scenarios, and Pharmacological Treatment of Neuropathic Pain documents with agreed changes and send to RDTC for addition to APC website.**

4e Erectile Dysfunction Guideline

The final draft of a new updated CD&D guideline for erectile dysfunction was presented to the

group for approval.

The new guideline and commissioning policy have been produced because North Durham CCG has been identified as an outlier with regard to prescribing for erectile dysfunction. The CCG Exec therefore supports a restriction on prescribing as a result. This change in policy will limited prescribing on PDE-5 inhibitors to current formulary choices and those patients meeting the NHS SLS criteria minus psychological distress which has been removed from the SLS list unless generic sildenafil is used.

The guideline was approved subject to the following amendments:

- Tadalafil once daily being included in the guideline as not approved as on DNP list.
- Page 10 – change avoid taking PDE-5 inhibitors with a heavy meal to ideally take before a meal and avoid taking after a heavy meal

The associated updated County Durham & Darlington Commissioning Policy Statement on Erectile Dysfunction was presented to the group for information.

ACTION:

- **Nicole Theobald (NECS) to update guideline with approved amendments and send to RDTC for addition to APC website.**
- **Nicole Theobald (NECS) to produce a one page summary detailing the changes made to the local Erectile Dysfunction Commissioning Policy (e.g. changes to quantity to be prescribed) to support implementation.**

Part 5 – Standing items (for information only)

5a Formulary Steering Group Minutes June 2017
For information.

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

5c TEWV D&T Annual Report 2016/17
For information.

5d CD&D FT Clinical Standards and Therapeutics Committee Minutes June 2017
Not yet available.

5e CD&D D&T CAG April 2017 & June 2017 Minutes
None available – meetings cancelled.

5f High Cost Drugs Group Minutes June 2017
For information.

5g NTAG Minutes June 2017
Not yet available.

5h RDTC Horizon scanning – July & August 2017
For information.

5i MHRA Drug Safety Update – July & August 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
June 2017 meeting cancelled.

Chairman's Action
Nil

Any Other Business
Amlodipine and Citalopram Generics
It was brought to the attention of the APC that prices for Amlodipine and Citalopram Generics are increasing due to problems with a generic manufacturing facility in India. This has the potential to affect a number of generics.

Date and time of next meeting:
Thursday 2nd November 2017 11.30am – 2.30pm
Board Room, Appleton House, Durham