

County Durham and Darlington Area Prescribing Committee

Thursday 6th September 2018

9am – 12noon

Room 2 Education Centre, Lanchester Road Hospital, Durham

Present

Dr Ian Davidson, Director of Quality & Safety, North Durham CCG (Chair)
Gavin Mankin, RDTA Representative (Professional Secretary)
Dan Newsome, Medicines Optimisation Pharmacist, NECS
Joan Sutherland, Medicines Optimisation Lead, North Durham CCG
Kate Huddart, Senior Pharmaceutical Advisor, DDES CCG
Chris Williams, Chief Pharmacist, TEWV FT
Dr Wolfgang Kuster, Associate Clinical Director, TEWV FT
Jamie Harris, Chief Pharmacist, CDDFT
Sarah McGeorge, Nurse Consultant, TEWV FT
Brewis Henderson, Patient Representative
Claire Jones, Public Health Pharmacist, Durham County Council (from item 4a)
Beverley Walton, Lead Clinical Pharmacist, CD&DFT
Dr Neil Middleton, GP Prescribing Lead, DDES CCG
Dr Esther Sheard, GP Prescribing Lead, North Durham CCG (from item 2d to item 4a)
Rob Pitt, LPC representative

In attendance

Nil

The meeting was not quorate and all decisions made would need agreement from members not present via email post-meeting.

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

1a Apologies for absence:

Chris Cunnington-Shore, Catherine Harrison, Peter Foster, Shafie Kamaruddin, Rosie England

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:

None declared

1c Minutes of the previous APC meeting held 5th July 2018

The minutes were accepted as a true and accurate record.

The decision summary of the July 2018 meeting was accepted as a true and accurate record.

1d Matters Arising/Action Log

Actions from July 2018 meeting not on the agenda or action log

Nil

Action Log

TEWV Drug & Therapeutics Committee Feedback – May 2018

Links have been checked on APC website to ensure ease of use. ITEM NOW CLOSED.

Hyperprolactinaemia Guidelines to come to November 2018 APC.

Annual report came to May 2018 APC for information. ITEM NOW CLOSED.

TEWV Safe Transfer of Prescribing Guidance

The Drugs for Dementia section requires revision to fall into line with revised NICE guidance. On today's agenda. ITEM NOW CLOSED.

Lithium Audit in County Durham

On today's agenda.

Sildenafil for Raynaud's Disease

Information to be brought back as to rationale for RED status in NoT and Tees before long term RAG status agreed. NoT FSC minutes 2009: "It was also noted that because of NHS restrictions on the prescribing of drugs used to treat erectile dysfunction such as sildenafil and tadalafil, these drugs would have to be given a 'RED' classification if used to treat Reynaud's syndrome". Suspect cost played its part and the off label use as well. ITEM NOW CLOSED.

Hydroxycarbamide Shared Care

On today's agenda. ITEM NOW CLOSED.

NHSE Guidance – Conditions for Which Over the Counter Items Should Not Routinely Be Prescribed in Primary Care

OTC annotation has been added to identified products on the formulary. ITEM NOW CLOSED.

Regional work to come to APC once available.

CD&D APC Asthma Guideline – updated

Updated guideline has been added to APC website. ITEM NOW CLOSED.

To circulate steroid inhaler dose equivalence chart. ITEM NOW CLOSED.

CD&D APC Emollient Prescribing for Dry Skin Conditions – updated

On today's agenda. ITEM NOW CLOSED.

Homely Remedies Policy

To be discussed at November 2018 APC.

Regional Insulin and Anticoagulation Incidents

On today's agenda.

Valproate Pregnancy Risk Prevention Programme

On today's agenda.

CDDFT palliative care prescription ("Red Kardex") vs. regional palliative care prescription

On today's agenda.

Historic Actions

Subcutaneous methotrexate

Contracting are now producing a final options paper.

ACTION:

- **ID/JS to chase up Contracting for final options paper.**

CDDFT Representatives to APC

No update available on progress seeking further consultant representation from CDDFT.

Osteoporosis Guideline

Update noted this will include updated commissioning guidance around the prescribing of Denosumab by GPs. Draft to be presented at November 2018 APC for approval.

Ciclosporin Eye Drops

No update required until July 2019.

Update to CD&D Drug Monitoring Document – Testosterone

A shared care guideline for testosterone is still in development.

Outpatient Prescribing Requests

The issues around the CDDFT Outpatient Treatment Recommendation form have been raised within CDDFT, and discussions have taken place between the LMC and CDDFT. Clinicians within CDDFT have been made aware of their responsibility for counselling patients with regard to new medicines following an outpatient consultation, and asked to ensure the use the forms and complete outpatient letters correctly.

It is hoped the new structure of the outpatient letter which follow a nationally agreed template will address these issues and the forms may no longer be required in the near future. The new letter structure should also include a statement that clinicians within CDDFT are responsible for counselling patients about a new medication or medication changes.

A further update will provided at the November 2018 APC.

ACTION:

- **JH to present an update on progress implementing new format of outpatient letters and the continued need for the current Outpatient Treatment Recommendation forms at November 2018 APC.**

NE&C Guidance for Management of Cow's Milk Allergy – draft for comment

Final draft for approval on today's agenda.

IBD Pathway

Has now been discussed and approved by High Cost Drugs Subgroup. The paperwork is being reviewed to ensure that have record of what has been agreed and ok to deviate from NICE guidance.

Antimicrobial Resistance and Performance Locally Against National Targets

Report will be presented to APC in Dec 2018.

Palliative Care Medicines Review

The list of medicines and stock levels has now been reviewed.

The list of participating pharmacies has been reviewed taking into account opening hours and location in order to provide optimum coverage. This list of pharmacies is going to LPC for approval and then will require some contracts to be updated.

Paper containing up to date list of drugs required to be stocked by participating pharmacies in CD&D was approved by the APC.

ACTION:

- **CD&D LPC to approve recommended list of participating pharmacies taking into account opening hours and location in order to provide optimum coverage.**

- **NECS to update list of medicines and participating pharmacies on C&D APC website once approved and contracts in place.**

Algorithm for the Pharmacological Management of Depression in Children and Young People

Link through to Transfer of Prescribing document is still to be added.

NHSE Primary Care Responsibilities in Regard to Request by On-line Medical Service Providers to Prescribe Hormone Treatments for Transgender People

A letter from the Chair of APC supported the LMC position has now been sent.

CD&D Drug Monitoring Guideline – updated

MHRA have responded indicating their guidance relating to LFT monitoring for Statins will remain unchanged. Still awaiting response from FATS group.

ACTION:

- **DN to chase up response from FATS group.**

CD&D APC Atrial Fibrillation Guideline

Still under review by CDDFT. To be discussed in September 2018.

Part 2 – Mental Health

2a TEWV Drug & Therapeutics Committee Feedback – July 2018

CW presented to the APC a briefing report highlighting the main issues discussed at the recent TEWV D&T.

2b Valproate Pregnancy Risk Prevention Programme

A draft Shared Care Guideline produced by TEWV to support local implementation of the Valproate Pregnancy Risk Prevention Programme was presented to and approved by the APC. CDDFT confirmed they are happy with the document from their perspective and will share with their clinical leads. CDDFT are also doing some work on clarifying the need to check the status of each patient when admitted acutely to secondary care.

The definition of child bearing potential was also discussed and clarity was asked for some possible exceptions plus need for extra category on the risk acknowledgment form that needs to be completed to address/acknowledge some of these possible exceptions. It is believed that this has been raised nationally with the MHRA.

ACTION:

- **CW to add APC logo and version control to Valproate Shared Care Guideline once approved by TEWV D&T and then publish on web.**
- **GM to add link to shared care guideline on APC website and CD&D formulary.**

2c TEWV Safe transfer of prescribing guidance

The document has had some minor updates and was circulated for information.

2d Dementia Pathway – updated

The updated draft Dementia Pathway was presented to and approved by the APC. This has been updated to reflect the changes to NICE guidance published in June 2018. It was agreed locally that it was still appropriate for memantine and the acetylcholinesterase inhibitors to remain GREEN+ drugs on the formulary.

2e Lithium Audit in County Durham

Update deferred until November 2018 APC.

ACTION:

- **GM to add to November 2018 APC agenda.**

Part 3 – General

3a Appeals against previous APC decisions

None received.

3b Update from Formulary Subgroup for July 2018 APC

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

Formulary Updates since July 2018 APC for approval including RAG changes

Approved with suggested changes to RAG recommendation as follows:

NICE Technology Appraisal/Guidance Title and date published	Date issued	Current formulary status	Recommended action for APC
<p><u>TA521: Guselkumab for treating moderate to severe plaque psoriasis</u> Commissioning: CCG Guselkumab is recommended as an option for treating plaque psoriasis in adults, only if:</p> <ul style="list-style-type: none"> • the disease 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 • the disease 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 and • the company provides the drug according to the commercial arrangement. <p>Stop guselkumab treatment at 16 weeks if the psoriasis has not responded adequately.</p>	13/06/18	On formulary in chapter 13.5.3 as a RED drug, with link to TA521.	No further action.
<p><u>TA522: Pembrolizumab for untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable</u> Commissioning: NHSE Pembrolizumab is recommended for use within the Cancer Drugs Fund as an option for untreated locally advanced or metastatic urothelial carcinoma in adults when cisplatin-containing chemotherapy is unsuitable, only if:</p> <ul style="list-style-type: none"> • pembrolizumab is stopped at 2 years of uninterrupted treatment or earlier if the disease progresses and • the conditions of the managed access agreement for pembrolizumab are followed 	13/06/18	On formulary in chapter 8.1.5 as a RED drug.	Add link to TA522 to chapter 8.1.5

<p><u>TA522: Pembrolizumab for untreated PD-L1-positive locally advanced or metastatic urothelial cancer when cisplatin is unsuitable (update)</u> Commissioning: NHSE Guidance updated because the EMA restricted the use of pembrolizumab for untreated urothelial carcinoma to adults with high levels of PD-L1.</p>	<p>24/7/18</p>	<p>As above</p>	<p>As above</p>
<p><u>TA523: Midostaurin for untreated acute myeloid leukaemia</u> Commissioning: NHSE Midostaurin is recommended, within its marketing authorisation, as an option in adults for treating newly diagnosed acute FLT3-mutation-positive myeloid leukaemia with standard daunorubicin and cytarabine as induction therapy, with high-dose cytarabine as consolidation therapy, and alone after complete response as maintenance therapy. It is recommended only if the company provides midostaurin with the discount agreed in the patient access scheme.</p>	<p>13/06/18</p>	<p>Not on formulary.</p>	<p>Add to formulary in chapter in chapter 8.1.5 with link to TA523</p>
<p><u>TA524: Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma</u> Commissioning: NHSE Brentuximab vedotin is recommended as an option for treating CD30-positive Hodgkin lymphoma in adults with relapsed or refractory disease, only if:</p> <ul style="list-style-type: none"> • they have already had autologous stem cell transplant or • they have already had at least 2 previous therapies when autologous stem cell transplant or multi-agent chemotherapy are not suitable and • the company provides brentuximab vedotin according to the commercial arrangement 	<p>13/06/18</p>	<p>On formulary in chapter 8.1.5 as a RED drug.</p>	<p>Add link to TA524 to chapter 8.1.5</p>
<p><u>TA525: Atezolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy</u> Commissioning: NHSE Atezolizumab is recommended as an option for treating locally advanced or metastatic urothelial carcinoma in adults who have had platinum-containing chemotherapy, only if:</p> <ul style="list-style-type: none"> • atezolizumab is stopped at 2 years of uninterrupted treatment or earlier if the disease progresses and • the company provides atezolizumab with the discount agreed in the patient access scheme. 	<p>13/06/18</p>	<p>On formulary in chapter 8.2.4 as a RED drug.</p>	<p>Add link to TA525 to chapter 8.2.4</p>

<p><u>TA526: Arsenic trioxide for treating acute promyelocytic leukaemia</u> Commissioning: NHSE Arsenic trioxide is recommended, within its marketing authorisation, as an option for inducing remission and consolidation in acute promyelocytic leukaemia (characterised by the presence of the t[15;17] translocation or the PML/RAR-alpha gene) in adults with:</p> <ul style="list-style-type: none"> • untreated, low-to-intermediate risk disease (defined as a white blood cell count of 10x10³ per microlitre or less), when given with all-trans-retinoic acid (ATRA) • relapsed or refractory disease, after a retinoid and chemotherapy. 	<p>13/06/18</p>	<p>On formulary in chapter 8.2.4 as a RED drug</p>	<p>Add link to TA526 to chapter 8.2.4</p>
<p><u>TA527: Beta interferons and glatiramer acetate for treating multiple sclerosis</u> Commissioning: NHSE Interferon beta- 1a is recommended as an option for treating multiple sclerosis, only if:</p> <ul style="list-style-type: none"> • the person has relapsing–remitting multiple sclerosis and • the companies provide it according to commercial arrangements. <p>Interferon beta- 1b (Extavia) is recommended as an option for treating multiple sclerosis, if:</p> <ul style="list-style-type: none"> • the person has relapsing–remitting multiple sclerosis and has had 2 or more relapses within the last 2 years or • the person has secondary progressive multiple sclerosis with continuing relapses • the company provides it according to the commercial arrangement. <p>Glatiramer acetate is recommended as an option for treating multiple sclerosis, only if:</p> <ul style="list-style-type: none"> • the person has relapsing–remitting multiple sclerosis and • the company provides it according to the commercial arrangement. <p>Interferon beta- 1b (Betaferon) is not recommended within its marketing authorisation as an option for treating MS. These recommendations are not intended to affect treatment with a beta interferon or glatiramer acetate that was started in the NHS before this guidance was published.</p>	<p>27/06/18</p>	<p>On formulary in chapter 8.2.4 as RED drugs</p>	<p>Add link to TA527 to chapter 8.2.4</p>
<p><u>TA217: Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (update)</u> Commissioning: CCG Updated in line with NG97.</p>	<p>20/06/18</p>	<p>All on formulary in chapter 4.11 as GREEN+ drugs.</p>	<p>Add link to TA217 to chapter 4.11.</p>

<p><u>TA528: Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer</u> Commissioning: NHSE Niraparib is recommended for use within the Cancer Drugs Fund as an option for treating relapsed, platinum-sensitive high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to the most recent course of platinum-based chemotherapy in adults, only if:</p> <ul style="list-style-type: none"> • they have a germline BRCA mutation and have had 2 courses of platinum-based chemotherapy or • they do not have a germline BRCA mutation and have had 2 or more courses of platinum-based chemotherapy and • the conditions in the managed access agreement for niraparib are followed. 	04/07/18	Not on formulary	Add to formulary in chapter 8.2.4 with link to TA528
<p><u>TA529: Crizotinib for treating ROS1-positive advanced non-small-cell lung cancer</u> Commissioning: NHSE Crizotinib is recommended for use within the Cancer Drugs Fund as an option for treating ROS1-positive advanced non-small-cell lung cancer (NSCLC) in adults, only if the conditions in the managed access agreement are followed.</p>	04/07/18	On formulary in chapter 8.1.5 as a RED drug.	Add link to TA529 to chapter 8.1.5
<p><u>TA530: Nivolumab for treating locally advanced unresectable or metastatic urothelial cancer after platinum-containing chemotherapy</u> Commissioning: NHSE Nivolumab is not recommended, within its marketing authorisation, for treating locally advanced unresectable or metastatic urothelial carcinoma in adults who have had platinum-containing therapy.</p>	04/07/18	On formulary in chapter 8.2.4 as a RED drug.	Add link to TA530 to chapter 8.2.4
<p><u>TA531: Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer</u> Commissioning: NHSE Pembrolizumab is recommended as an option for untreated PD-L1-positive metastatic non-small-cell lung cancer (NSCLC) in adults whose 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, only if:</p> <ul style="list-style-type: none"> • pembrolizumab is stopped at 2 years of uninterrupted treatment or earlier in the event of disease progression and • the company provides pembrolizumab according to the commercial access agreement. 	18/07/18	On formulary in chapter 8.1.5 as a RED drug.	Add link to TA531 to chapter 8.1.5

<p>TA532: Cenegermin for treating neurotrophic keratitis Commissioning: NHSE Cenegermin is not recommended, within its marketing authorisation, for treating moderate or severe neurotrophic keratitis in adults.</p>	18/07/18	Not on formulary	No further action
<p>TA533: Ocrelizumab for treating relapsing–remitting multiple sclerosis Commissioning: NHSE Ocrelizumab is recommended as an option for treating relapsing–remitting multiple sclerosis in adults with active disease defined by clinical or imaging features, only if:</p> <ul style="list-style-type: none"> • alemtuzumab is contraindicated or otherwise unsuitable and • the company provides ocrelizumab according to the commercial arrangement. 	25/07/18	Not on formulary.	Add to formulary in chapter 8.2.4 with link to TA533
<p>TA492: Atezolizumab for untreated PD-L1-positive locally advanced or metastatic urothelial cancer when cisplatin is unsuitable (update) Commissioning: NHSE Guidance updated because the EMA restricted the use of atezolizumab for untreated urothelial carcinoma to adults with high levels of PD-L1.</p>	12/07/18	On formulary in chapter 8.2.4 as a RED drug, in line with TA492.	No further action
<p>NG97: Dementia: assessment, management and support for people living with dementia and their carers This guideline covers diagnosing and managing dementia (including Alzheimer’s disease). It aims to improve care by making recommendations on training staff and helping carers to support people living with dementia.</p>	20/06/18	All drugs on formulary in chapter 4.11 as GREEN+.	Add link to NG97 to chapter 4.11.
<p>NG98: Hearing loss in adults: assessment and management This guideline covers some aspects of assessing and managing hearing loss in primary, community and secondary care. It aims to improve the quality of life for adults with hearing loss by advising healthcare staff on assessing hearing difficulties, managing earwax and referring people for audiological or specialist assessment and management.</p>	21/06/18	For info	No further action
<p>NG99: Brain tumours (primary) and brain metastases in adults Commissioning: NHSE This guideline covers diagnosing, monitoring and managing any type of primary brain tumour or brain metastases in people aged 16 or over. It aims to improve diagnosis and care, including standardising the care people have, how information and support are provided, and palliative care.</p>	11/07/18	For info	No further action

<p>NG100: Rheumatoid arthritis in adults: management Commissioning: CCGs This guideline covers diagnosing and managing rheumatoid arthritis. It aims to improve quality of life by ensuring that people with rheumatoid arthritis have the right treatment to slow the progression of their condition and control their symptoms. People should also have rapid access to specialist care if their condition suddenly worsens</p>	<p>11/07/18</p>	<p>Contains recommendations on:</p> <ul style="list-style-type: none"> conventional DMARDs (cDMARDs): methotrexate, leflunomide, sulfasalazine, hydroxychloroquine glucocorticoids NSAIDs Biologics and synthetic DMARDs 	<p>Add link to start of Chapter 10</p>
<p>NG101: Early and locally advanced breast cancer: diagnosis and management Commissioning: CCGs & NHSE This guideline covers diagnosing and managing early and locally advanced breast cancer. It aims to help healthcare professionals offer the right treatments to people, taking into account the person's individual preferences</p>	<p>18/07/18</p>	<p>Contains recommendations on tamoxifen (including extended use), aromatase inhibitors, chemotherapy & adjuvant chemotherapy, adjuvant bisphosphonates.</p>	<p>No further action</p>
<p>NTAG Recommendations</p>	<p>Date issued</p>	<p>Current formulary status</p>	<p>Recommended action for APC</p>
<p>No new recommendations since last meeting.</p>			
<p>RMOC Recommendations</p>	<p>Date issued</p>	<p>Current formulary status</p>	<p>Recommended action for APC</p>
<p>Insulin preparations: RMOC recommendations of safety considerations for formulary decision making At its meeting on 18th April 2018 the Regional Medicines Optimisation Committee (RMOC) (Midlands and East) reviewed issues pertaining to safety considerations when adopting any insulin preparation onto a local formulary.</p>	<p>25/06/18</p>	<p>For info</p>	<p>FSG adopts this safety assessment when considering a new insulin formulary application.</p>
<p>Free of Charge (FOC) Medicines Schemes: RMOC Advice for adoption as local policy Executive summary: 1.1 A free of charge medicines scheme is defined as an arrangement where a UK licensed or unlicensed medicine is provided free of charge by the pharmaceutical company to an individual patient or an identified cohort of patients. 1.2 Commissioners and providers must only undertake a free of charge scheme if the principles outlined in this policy are followed. 1.3 Trusts or commissioners should not sign up to a free of charge (FOC) scheme which is solely offering a licensed medicine free of charge in advance of NICE approval.</p>	<p>28/07/18</p>	<p>For info</p>	<p>To come to APC once consider by High Cost Drugs Subgroup</p>

Drug Safety Advice	Date issued	Current formulary status	Recommended action for APC
Dolutegravir (Tivicay▼, Triumeq▼, Juluca▼): signal of increased risk of neural tube defects; do not prescribe to women seeking to become pregnant; exclude pregnancy before initiation and advise use of effective contraception	22/06/18	Not on formulary	No further action
Denosumab (Xgeva▼) for giant cell tumour of bone: risk of clinically significant hypercalcaemia following discontinuation	22/06/18	On formulary in chapter 6.6.2.2	Add link to chapter 6.6.2.2
Denosumab (Xgeva▼) for advanced malignancies involving bone: study data show new primary malignancies reported more frequently compared to zoledronate	22/06/18	On formulary in chapter 6.6.2.2	Add link to chapter 6.6.2.2
Letters sent to healthcare professionals in May 2018 In May 2018, letters were sent to healthcare professionals about: <ul style="list-style-type: none"> • Azithromycin: increased rate of relapses of haematological malignancies and mortality in hematopoietic stem cell transplantation (HSCT) patients treated with azithromycin • Lynparza▼ (Olaparib): Risk of medication errors with new pharmaceutical form • Xgeva▼ (denosumab): risk of new primary malignancy • Lymphoseek (tilmanocept) radiopharmaceutical preparation: temporary extension of shelf life of lot F03016002 • ReoPro (abciximab) 2 mg/mL solution for injection or infusion: Indefinite Supply Shortage • Tivicay▼ (dolutegravir), Triumeq▼ (dolutegravir, abacavir, lamivudine), Juluca▼ (dolutegravir, rilpivirine): neural tube defects reported in infants born to women exposed to dolutegravir at the time of conception 	22/06/18	For info	No further action
Darunavir boosted with cobicistat: avoid use in pregnancy due to risk of treatment failure and maternal-to-child transmission of HIV-1	17/7/18	On formulary in chapter 5.3.1 as a RED drug	Add link to DSU to chapter 5.3.1
Pressurised metered dose inhalers (pMDI): risk of airway obstruction from aspiration of loose objects	17/7/18	Multiple devices on formulary in chapter 3	Add link to DSU to chapter 3
Eltrombopag (Revolade): reports of interference with bilirubin and creatinine test results	17/7/18	Not on formulary	No further action

<p><u>Parenteral amphotericin B: reminder of risk of potentially fatal adverse reaction if formulations confused</u></p>	<p>17/7/18</p>	<p>On formulary in chapters 5.2 (Fungizone® & Abelcet®) & 12.3.2 (oral solution) as a RED drug.</p>	<p>Add link to DSU to chapter 5.2.</p>
<p><u>Medicines taken during pregnancy: please report suspected adverse drug reactions, including in the baby or child, on a Yellow Card</u></p>	<p>17/7/18</p>	<p>For info</p>	<p>No further action</p>
<p><u>Letters sent to healthcare professionals in June 2018</u></p> <ul style="list-style-type: none"> • Cetrotide (cetorelix acetate): Risk of missed doses or loss of sterility when using new syringe with different design • Eperzan ▼ (albiglutide): reminder letter regarding the discontinuation • Darunavir/cobicistat: Increased risk of treatment failure and increased risk of mother-to-child transmission of HIV infection when darunavir and cobicistat coadministered, due to low exposure values during the second and third trimesters of pregnancy • Keytruda ▼ (pembrolizumab): Restriction of indication for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin-containing chemotherapy • Denzapine 50 mg/mL Oral Suspension (clozapine): risk of loss of efficacy due to crystallisation of the suspension; always follow instructions for use, including 24 hours before first dosing , see company-led recall • Bleo-Kyowa (bleomycin sulphate), powder for solution for injection: use 5 micron filter during IV infusion or pre-injection, see class 4 medicines defect information 	<p>17/7/18</p>	<p>For info</p>	<p>No further action</p>
<p>NHS <u>Patient Safety Alerts</u></p>	<p>Date issued</p>	<p>Current formulary status</p>	<p>Recommended action for APC</p>
<p><u>Resources to support safer modification of food and drink.</u> A resource alert has been issued to eliminate use of the imprecise term 'soft diet' and assist providers with safe transition to the International Dysphagia Diet Standardisation Initiative (IDDSI) framework, which introduces standard terminology to describe texture modification for food and drink.</p>	<p>27/06/18</p>	<p>For info</p>	<p>No further action – local guidance already issued.</p>

Requested formulary amendments	BNF Chapter	Reasoning	Recommended action for APC
Humulin R Insulin – delete from formulary	6.1.1	High strength unlicensed insulin which is no longer used. Replaced by combination of Toujeo® and Humalog 200®	Delete from formulary.
Emollient Bath Additives – delete from formulary	13.2.1.1	On basis of BATHE trial No evidence to support routine use of bath emollients. Emollients can be and should be used for washing (except 50:50 WSP Liquid Paraffin Ointment). Risk of slipping due to emollient application in bath – caution advised. Dermatology confirmed that they do not routinely prescribe these products	Delete from formulary.
<p>Steroid creams containing antimicrobials</p> <ul style="list-style-type: none"> • Trimovate – remove from formulary due to ongoing supply issues • Highlight pack sizes that are available OTC • Add Fucibet®, Synalar N®, Synalar C® and Lotriderm® as cheaper than current potent steroid choices • Betamethasone 0.1% with clioquinol 3%, Betamethasone 0,1% with neomycin 0.5%, Fucidin H®, Nystaform HC®, Terra-Cortil® and Dermovate NN® make second line due to cost. 	13.4	See previous column.	<ul style="list-style-type: none"> • Trimovate – remove from formulary due to ongoing supply issues • Highlight pack sizes that are available OTC • Add Fucibet®, Synalar N®, Synalar C® and Lotriderm® as cheaper than current potent steroid choices • Betamethasone 0.1% with clioquinol 3%, Betamethasone 0,1% with neomycin 0.5%, Fucidin H®, Nystaform HC®, Terra-Cortil® and Dermovate NN® make second line due to cost.

Naloxegol – consider changing from Green+ to Green	1.6.6	Request received from Prof Yiannakou to change RAG status to reduce referrals to secondary care. FSG feel Green+ status is appropriate to ensure only used for OIC and ensure other laxative therapy is reviewed. All other newer laxatives are also Green+ e.g. prucalopride.	No change from current GREEN+ status
Tacrolimus(oral) for non-transplant indications – consider changing from AMBER to RED	8.2.2	Confirmed no local shared care guideline is in place for oral tacrolimus for non-transplant indications.	Change from AMBER to RED.
Buprenorphine 35microgram/hr, 52.5microgram/hr & 70microgram /hr 96 hour patches – add to formulary	4.7.2	To avoid confusion with the 72 hour patches of the same strength and 96 hour buprenorphine patches are the most commonly used locally.	Add to formulary as Green alt (the same as the weekly patches).
Mebeverine Liquid – to annotate as 2 nd line	1.2.2	High cost vs tablets	Annotate formulary to say 2nd line.

ACTION:

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

3c New Drug Applications

Nil this month.

3d Shared Care Guidelines for Approval

Hydroxycarbamide

The updated shared care guideline with the changes requested at July 2018 APC around appropriate blood monitoring and indications (CML and sickle cell) were approved.

Mycophenolate

The updated shared care guideline with the following additions was approved:

- Immune disorders of nervous system as an additional indication
- Clarification that it is the specialist's responsibility to immunise patients found not to have varicella zoster immunity.

Azathioprine, 6-Mercaptopurine and Ciclosporin

The updated shared care guidelines with the following addition were approved:

- Clarification that it is the specialist's responsibility to immunise patients found not to have varicella zoster immunity.

ACTION:

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

The APC also discussed and agreed to add space on the shared care request form/letter for information on any patient specific monitoring requirements to be included.

CDDFT also agreed to explore including information on shared care drugs such as current dose and current monitoring plus any changes required in outpatient review letters, and the possibility

of having a DMARD Annual Review Letter.

ACTION:

- **BW to explore including information on shared care drugs such as current dose and current monitoring plus any changes required in outpatient review letters, and the possibility of having a DMARD Annual Review Letter.**

3e Chapter 11 (Eye) of Formulary

The reviewed and updated Chapter 11 of the Formulary was approved. This has been reviewed with the ophthalmologists at CDDFT and compared against the North of Tyne plus Sunderland formularies. It also was agreed to review the possible need to include the Hylo range of eye drops in the formulary with Sunderland because of their apparent high usage locally which may be related to some local ophthalmology services being provided by Sunderland.

ACTION:

- **GM to update the online formulary with the approved changes once ratification received from Darlington/HAST CCG Joint Exec.**
- **JH/GM to review with Sunderland if the Hylo range of eye drops need to be included in the CD&D formulary.**

3f NTAG Update

A verbal update on the September 2018 NTAG was given to the group.

3g CDDFT CSTC Update September 2018 – verbal update

A verbal update was given.

3h RMOC Update

The following updates from RMOC were circulated to the group for information:

- North RMOC Update – June 2018
- Adalimumab Biosimilar – update 3
- Insulin Preparations – safety factors for local formulary decision making

3i Ulipristal acetate for uterine fibroids – changes to product license

The group discussed and agreed that following the outcome of the MHRA safety review into Ulipristal acetate (Esysma®) for uterine fibroids and the subsequent changes in product license, including more restrictive licensed indications, that it should be changed from GREEN+ to RED on the formulary

ACTION:

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

3j Changes to High Cost Drugs Subgroup Terms of Reference

The revised High Cost Drugs Subgroup were approved by the group.

3k Collaborative Working with Tees Medicines Governance Group

A verbal update was given.

3l CD&D Wound Care Formulary – reviewed and updated

A paper on the County Durham & Darlington wound care product supply project as an alternative to FP10 supply was presented to the APC and the APC was briefed on plans for its implementation.

The concerns of the LPC with regard to the changes in the way wound care products are supplied locally were raised. The LPC are very unhappy at this proposal and are unable to support it. The APC noted these concerns and asked that they be looked at by the project team. The role of the APC in this issue is not to approve the supply process, that is for the CCGs/Trust but to approve formulary itself. The Chair re-iterated the value the APC places on the

involvement of community pharmacy in its work and in the local healthcare.

The APC then moved on to discuss the revised County Durham & Darlington Wound Care Formulary itself. It was agreed not to approve the revised formulary today but to take Chair's Action once information on the cost of different dressings is added, and the involvement of practice nurses in drawing up the revised formulary was confirmed.

ACTION:

- **DN to confirm with KH with practice nurses were involved in drawing up the revised formulary.**
- **RP to forward DN LPC concerns around off-prescription model of dressings supply included concerns about legality.**

Part 4 – Physical Health

4a CD&D APC Emollient Prescribing for Dry Skin Conditions – updated

Following the discussions at the July 2018 APC around the continued inclusion of bath and shower emollients in the local formulary it has been confirmed with Dermatology that they can be removed. This is following the recent publication of the BATHE trial. The updated CD&D APC Emollient Prescribing Guidelines has been updated to reflect this and was approved by the APC.

ACTION:

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

4b NE&C Guidance for Management of Cow's Milk Allergy

The final draft of a regional guideline for the management of Cow's Milk Allergy produced by the Northern Paediatric Allergy Group (NPAG) was presented and approved by the APC subject to the following minor change:

- Titration Guide to include both imperial and metric measurements

ACTION:

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

4c School Medicines FAQ

The updated County Durham Managing Medicines in Schools FAQ was approved subject to the following amendments:

- Inclusion of information on diabetic care plans and that they contain useful information.
- Clarify what schools should do about handing over medicines to third party after-school clubs.

ACTION:

- **CJ to make suggested changes and circulate final version.**

4d Regional Insulin and Anticoagulation Incidents

It was agreed there was no further action for the APC as this stage.

4e CDDFT palliative care prescription ("Red Kardex") vs. regional palliative care prescription

It was noted that SystemOne template has now been finalised but it needs to be replicated in EMIS. It was also highlighted that there are no plans to get rid of paper copies of the chart at present.

It was agreed to circulate the latest version of the electronically generated chart outside of the

meeting for Chair's approval.

ACTION:

- **JH to circulate the latest version of the electronically generated chart outside of the meeting for Chair's approval.**

Part 5 – Standing items (for information only)

- 5a Formulary Steering Group Minutes June 2018**
For information.
- 5b TEWV D&T Minutes May 2018**
For information.
- 5c CD&D FT Clinical Standards and Therapeutics Committee Minutes June 2018**
Not yet available.
- 5d High Cost Drugs Group Minutes January, March & May 2018**
For information.
- 5e NTAG Minutes February 2018**
Not yet available.
- 5f RDTC Horizon scanning – July & August 2018**
For information.
- 5g MHRA Drug Safety Update – June & July 2018**
For information.
- 5h AHSN Medicines Optimisation Steering Group Minutes – December 2017**
Meeting was cancelled.
- 5i Tees Medicines Governance Group Recommendation Summary August 2018**
For information.
- 5j NE&C CCG Prescribing Forum Minutes – since January 2018**
Not yet available.
- 5k RMOC Minutes (North) – February 2018**
For information.
- 5l ND & DDES Joint Medicines Optimisation Subcommittee Minutes**
Not yet available.
- 5m NEAS Medicines Group Minutes – June 2018**
For information.

Chairman's Action

The following documents have been approved since the last meeting via Chair's Action:

- Nil

Any Other Business

CD&D Erectile Dysfunction Guideline

The updated guideline with the changes requested at the July 2018 APC was approved.

ACTION:

- **GM to arrange for document to be added to CD&D pages of NECS website**

Date and time of next meeting:

Thursday 1st November 2018, 9am – 12noon
Board Room, West Park Hospital, Darlington