

County Durham and Tees Valley Area Prescribing Committee

Thursday 9th July 2020
9am – 11.30am
Held Via Microsoft Teams

Present

Name	Job Title	Membership Capacity	Organisation	Jan 2020	Mar 2020	May 2020	July 2020
David Russell	GP Prescribing Lead (Darlington)	Clinician	Tees Valley CCG	✓	✓		✓
Deborah Giles	Medicines Optimisation Pharmacist	Pharmacist	Tees Valley CCG				
Peter Foster	GP Prescribing Lead	Clinician	County Durham CCG	✓			✓ (left at 10.20am)
Kate Huddart	Senior Pharmaceutical Advisor	Pharmacist	County Durham CCG	✓	✓		✓
	GP	Clinician	North Yorks CCG				
Susan Broughton	HRW Locality Lead Pharmacist	Pharmacist	North Yorks CCG	✓	Apols		Chris Ranson
Rupert Smith	GP Prescribing Lead	Clinician & Chair of FSG	Tees Valley CCG (HAST)	✓	✓		✓
Michaela Connolly	Clinical Pharmacist	Pharmacist	Tees Valley CCG (HAST)	Apols			
Ian Davidson (Chair)	Medical Director	Clinician	County Durham CCG	✓	Apols		✓
Joan Sutherland	Medicines Optimisation Lead	Pharmacist	County Durham CCG	✓	Charntel Gash		
Janet Walker	Medical Director	Clinician	Tees Valley CCG	✓	✓		✓
Alastair Monk	Medicines Optimisation Pharmacist	Pharmacist	Tees Valley CCG				✓
Shafie Kamaruddin	Consultant & Chair of CSTC	Clinician	CDDFT		✓		✓ (left at 10.30am)
Jamie Harris	Chief Pharmacist	Pharmacist	CDDFT	✓	✓		✓
		Clinician	NTHFT				
Chris Mallon	Formulary Pharmacist	Pharmacist	NTHFT	✓	✓		Apols
Andy Lloyd		Clinician	STFT		✓		✓
Helen Jones	Chief Pharmacist	Pharmacist	STFT	✓	✓		✓
Baxi Sinha		Clinician	TEWVFT	✓	Apols		✓
Chris Williams	Chief Pharmacist	Pharmacist	TEWVFT	✓	✓		✓
Julie Birch or Tanya Johnston	GP	LMC Rep		Apols	Apols		
Rob Pitt	Community Pharmacist	LPC Rep – County Durham		✓	✓		
Brent Foster	Community Pharmacist	LPC Rep – Tees		Apols			✓
Claire Jones	Public Health Pharmacist	Public Health Rep	Durham Council	✓	✓		Apols
Chris Cunnington - Shore		Service User Rep – County		Brewis Henderson	Brewis Henderson		✓

		Durham					
		Service User Rep - Tees					
Mark Pickering	Chief Finance Officer for Tees Valley CCG	Commissioning & Finance Rep	County Durham & Tees CCGs	✓	Apols		✓
Rosie England	Chief Pharmacist	NEAS	NEAS				
Ian Morris	Senior Medicines Optimisation Pharmacist	NECS	NECS				
Gavin Mankin	Principal Pharmacist Medicines Management	Professional Secretary	Regional Drug & Therapeutics Centre, Newcastle	✓	✓		✓

In attendance

Rahul Bhugra - Regional Drug & Therapeutics Centre – attending to support sharing of papers via MS Teams during meeting.

The meeting was quorate and remained quorate throughout with minimum number of stakeholder organisations represented plus Alastair Monk as the pharmacist representative from Tees Valley CCG.

To note Mark Duggleby is no longer employed as a prescribing lead GP by NY CCG (due to the merger) and so will not be attending any future meetings. NY CCG is currently considering how to include a NY GP rep to APC.

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

1. Apologies for Absence:

Claire Jones, Susan Broughton, Angela Dixon, Chris Mallon

2. 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:

Item 18: VTE Pathway: David Russell on occasions received payment from Bayer for giving talks on County Durham & Darlington Pathway and more recently for talks on medicolegal issues – noted by APC and agreed no action required as pathway reflects NICE guidance.

3. Minutes and Decision Summary of the Previous APC Meeting Held on 12th March 2020

The minutes were accepted as a true and accurate record with the following amendment:

- Attendance of Andy Lloyd to be included.
- Item 13, page 11 – to clarify that formulary application for Espranor® was not approved.

The decision summary of the March 2020 meeting was accepted as a true and accurate record.

4. Matters Arising Not On the Agenda

Nil.

5. Action Log

NICE TAs and MHRA Drug Safety Update – December 2019 & January 2020

RDTC have circulated and added approved updated APC position statement on Nefopam to APC pages of NECS website. Letter also sent to all local private hospitals to raise awareness of position statement.

Melatonin Shared Care – minor update RDTC to arrange for approved version to be added to APC pages of NECS website.

Now added to website. ITEM NOW CLOSED.

Melatonin Shared Care – minor update - RDTC to arrange for approved version to be added to APC pages of NECS website.

Now added to website. ITEM NOW CLOSED.

Methotrexate Oral Shared Care (County Durham & Darlington) - RDTC to arrange for approved version to be added to APC pages of NECS website.

Now added to website. ITEM NOW CLOSED.

Vitamins and Minerals Guidance - RDTC to arrange for approved version to be added to APC pages of NECS website.

Now added to website. ITEM NOW CLOSED.

Self-monitoring of Blood Glucose Guidance and Review of Blood Glucose Testing Strips and Meters - RDTC to arrange for approved version to be added to APC pages of NECS website.

Now added to website. ITEM NOW CLOSED.

Formulary Application Form – updated primary care finance section - RDTC to arrange for approved version to be added to APC pages of NECS website.

Now added to website and form circulated to formulary pharmacist at each of APC stakeholder Trusts. ITEM NOW CLOSED.

APC Terms of Reference and Membership - RDTC to circulate current APC Terms of Reference and membership to APC members to review prior to May 2020 APC.

Completed and comments received on July 2020 APC agenda for discussion.

Declarations of Interest Policy

Forms circulated. A few remain outstanding and will be chased up by the RDTC.

RMOC Liothyronine Guidance

No further update due to COVID-19.

Algorithm for Blood Glucose Lowering Therapy in Adults with Type 2 Diabetes

Work continues to explore the possibility of financial and health modelling of this guideline being done regionally or pan-regionally.

APC Workplan

On today's agenda for review in light of COVID-19.

NICE TAs and MHRA Drug Safety Update – October & November 2019 – TA607: Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease

Unable to find contact details for cardiology network so have asked formulary lead pharmacist in each Trust to seek guidance from their cardiologists particularly around what to do with historic patients who may be eligible and what tools exist to assess ischaemic risk plus bleeding risk. Further guidance was expected following regional cardiology meeting in March 2020. This is currently being followed by RDTTC.

Part 2 – Mental Health

6. TEWV Drug & Therapeutics Committee Feedback – May 2020

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

To note:

- TEWV Safe Transfer of Prescribing Guideline – APC approved updating wording for GREEN drugs to state that TEWV will not give a supply when they are giving advice rather than physically seeing the patient. In these circumstances the GP will be expected to prescribe the first supply.

7. TEWV Pharmacy & Medicines COVID-19 Advice

Latest version circulated for information.

8. Phenezine Tablet Shortage – June 2020

Latest guidance from TEWV circulated for information.

Part 4 – Formulary Issues

9. Appeals Against Previous APC Decisions

Nil for this meeting.

10. NICE TAs and MHRA Drug Safety Update – February 2020 to May 2020

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

NICE Technology Appraisal/Guidance Title and date published	Date issued	Current formulary status	Recommended action for APC
TA597: Dapagliflozin with insulin for treating type 1 diabetes (update) Commissioning: CCG, tariff included The measures of assessing haemoglobin A1c (HbA1c) in the recommendations have been changed to reflect those commonly used in the NHS. Other minor changes have been made to the recommendations to align them with dapagliflozins expected clinical use.	28/08/19 updated 12/02/20	On formulary in chapter 6.1.2.3 as a GREEN drug, with link to NICE TA.	No further action for APC.

<p>TA622: Sotagliflozin with insulin for treating type 1 diabetes Commissioning: CCG, tariff included Sotagliflozin with insulin is recommended as an option for treating type 1 diabetes in adults with a body mass index (BMI) of at least 27 kg/m², when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy, only if:</p> <ul style="list-style-type: none"> • sotagliflozin is given as one 200 mg tablet daily • they are on insulin doses of 0.5 units/kg of body weight/day or more and • they have completed a structured education programme that is evidence based, quality assured, delivered by trained educators and includes information about diabetic ketoacidosis, • treatment is started and supervised by a consultant physician specialising in endocrinology and diabetes treatment, and haemoglobin A1c (HbA1c) levels are assessed after 6 months and regularly after this. <p>Stop sotagliflozin if there has not been a sustained improvement in glycaemic control (that is, a fall in HbA1c level of about 0.3% or 3 mmol/mol).</p>	<p>12/02/20</p>	<p>Not on formulary. Sotagliflozin has been licensed since the spring of 2019 but is not yet launched in the UK. Launch planned for 2020.</p>	<p>No further action for APC at this stage. Launch will be highlighted in future horizon scanning.</p>
<p>TA623: Patiromer for treating hyperkalaemia Commissioning: CCG, tariff included Patiromer is recommended as an option for treating hyperkalaemia in adults only if used:</p> <ul style="list-style-type: none"> • in emergency care for acute life-threatening hyperkalaemia alongside standard care or • for people with persistent hyperkalaemia and stages 3b to 5 chronic kidney disease or heart failure, if they: <ul style="list-style-type: none"> ○ have a confirmed serum potassium level of at least 6.0 mmol/litre and ○ are not taking, or are taking a reduced dosage of, a renin-angiotensin-aldosterone system (RAAS) inhibitor because of hyperkalaemia and ○ are not on dialysis. <p>Stop patiromer if RAAS inhibitors are no longer suitable.</p>	<p>13/02/20</p>	<p>On formulary in Chapter 9.2.1.1 as not approved as per NTAG guidance.</p>	<p>Added to formulary in chapter 9.2.1.1 as RED drug initially and add link to TA623. Agreed to change to AMBER Specialist Initiation for use in patients with persistent hyperkalaemia. To remain RED for acute life-threatening hyperkalaemia.</p>
<p>TA624: Peginterferon beta-1a for treating relapsing–remitting multiple sclerosis Commissioning: NHSE Peginterferon beta-1a is recommended, within its marketing authorisation, as an option for treating relapsing–remitting multiple sclerosis in adults.</p>	<p>19/02/20</p>	<p>On formulary in chapter 8.2.4 as a RED drug for treatment of MS. Plegriidy brand is specified on formulary.</p>	<p>Add link to TA624 to chapter 8.2.4</p>
<p>TA625: Recombinant human parathyroid hormone for treating hypoparathyroidism (terminated appraisal) Commissioning: NHSE NICE is unable to make a recommendation about the use in the NHS of recombinant human parathyroid hormone for treating hypoparathyroidism because Shire Pharmaceuticals (now part of Takeda) did not provide an evidence submission. The company has advised NICE that there is a clinical study being done in the UK, so there is insufficient evidence to provide a submission for this appraisal at this stage.</p>	<p>04/03/20</p>	<p>Not listed.</p>	<p>No further action for APC.</p>
<p>TA627: Lenalidomide with rituximab for previously treated follicular lymphoma Commissioning: NHSE Lenalidomide with rituximab is recommended, within its marketing authorisation, as an option for previously treated follicular lymphoma (grade 1 to 3A) in adults. It is only recommended if the company provides lenalidomide according to the commercial arrangement.</p>	<p>07/04/20</p>	<p>Listed as RED drug in chapter 8.2.4</p>	<p>Add link to NICE TA</p>

<p>TA628: Lorlatinib for previously treated ALK-positive advanced non-small-cell lung cancer Commissioning: NHSE Lorlatinib is recommended, within its marketing authorisation, as an option for treating anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer (NSCLC) in adults whose disease has progressed after alectinib or ceritinib as the first ALK tyrosine kinase inhibitor or crizotinib and at least 1 other ALK tyrosine kinase inhibitor. It is recommended only if the company provides lorlatinib according to the commercial arrangement.</p>	13/05/20	Not listed	Add for formulary as RED drug in chapter 8.1.5 and add link to NICE TA.
<p>TA629: Obinutuzumab with bendamustine for treating follicular lymphoma after rituximab Commissioning: NHSE Obinutuzumab with bendamustine followed by obinutuzumab maintenance is recommended, within its marketing authorisation, as an option for treating follicular lymphoma that did not respond or progressed up to 6 months after treatment with rituximab or a rituximab-containing regimen. It is recommended only if the company provides it according to the commercial arrangement.</p>	13/05/20	Listed as RED drug in chapter 8.2.3	Add link to NICE TA
<p>TA630: Larotrectinib for treating NTRK fusion-positive solid tumours Commissioning: NHSE Larotrectinib is recommended for use within the Cancer Drugs Fund as an option for treating neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumours in adults and children if:</p> <ul style="list-style-type: none"> • the disease is locally advanced or metastatic or surgery could cause severe health problems and • they have no satisfactory treatment options. • It is recommended only if the conditions in the managed access agreement for larotrectinib are followed. 	27/05/20	Not listed	Add to formulary as RED drug in chapter 8.1.5 and add link to NICE TA.
Drug Safety Advice	Date issued	Current formulary status	Recommended action for APC
<p>Ingenol mebutate gel (Picato▼): suspension of the licence due to risk of skin malignancy Stop prescribing Picato and consider other treatment options for actinic keratosis as appropriate. The licence of ingenol mebutate (Picato) has been suspended as a precautionary measure while the European Medicines Agency (EMA) continues to investigate concerns about a possible increased risk of skin malignancy.</p>	12/02/20	Not on formulary currently.	No further action for APC
<p>Lemtrada ▼ (alemtuzumab): updated restrictions and strengthened monitoring requirements following review of serious cardiovascular and immune-mediated reactions A review of the benefits and risks of alemtuzumab (including fatal reactions) in the treatment of multiple sclerosis has now concluded and recommended a revised indication, additional contraindications, and strengthened monitoring requirements before, during and after treatment. Patients offered alemtuzumab should be alerted to the early risks of cardiovascular events and thrombocytopenia around the time of infusion and to the delayed risk of immune-mediated reactions. Healthcare professionals should inform patients what to do if they develop any symptoms of these disorders.</p>	12/02/20	On formulary in chapter 8.2.3 as a RED drug.	Add link to MHRA guidance.

<p>Valproate (Epilim ▼, Depakote ▼) pregnancy prevention programme: updated educational materials</p> <p>In January 2020, healthcare professionals received updated educational materials to support the valproate pregnancy prevention programme. Valproate is contraindicated in girls and women of childbearing potential, unless the conditions of the pregnancy prevention programme are met.</p>	12/02/20	On formulary in chapters 4.2, 4.7 & 4.8, with links to previous MHRA advice.	Add links to updated educational materials to all relevant chapters.
<p>Nexplanon (etonogestrel) contraceptive implants: new insertion site to reduce rare risk of neurovascular injury and implant migration</p> <p>Amended advice on the insertion site for Nexplanon contraceptive implants following concerns regarding reports of neurovascular injury and implants migrating to the vasculature (including the pulmonary artery).</p>	12/02/20	On formulary in chapter 7.3.2.2 as a GREEN drug.	Add link to MHRA guidance.
<p>Support Yellow Card: report suspected reactions in patients taking multiple medicines</p> <p>Be especially alert for adverse drug reactions (ADRs) in patients taking more than one medicine and report any suspected ADRs to the Yellow Card Scheme. Show your support for the MHRA's ADR awareness week campaign on 17–23 February 2020 by sharing material on social media and discussing with colleagues and patients the importance of reporting suspected side effects.</p>	12/02/20	For info	No further action for APC.
<p>Letters and drug alerts sent to healthcare professionals in January 2020</p> <ul style="list-style-type: none"> • Methotrexate for autoimmune diseases: recommendations to reduce potentially fatal dosing errors • Modafinil: potential risk of congenital malformations during pregnancy • Ecalta 100mg (anidulafungin): Solution for infusion must no longer be frozen • Lemtrada ▼ (alemtuzumab): Restricted indication, additional contraindications and risk minimisation measures (see accompanying Drug Safety Update) • Nexplanon (etonogestrel 68 mg, implant for subdermal use): update to the insertion and removal instructions to minimise the risks of neurovascular injury and implant migration (see accompanying Drug Safety Update) • ▼Picato (ingenol mebutate) – Suspension of the marketing authorisation due to risk of skin malignancy (see accompanying Drug Safety Update) • Valproate (Epilim ▼, Depakote ▼): Pregnancy Prevention Programme – revised educational materials • Class 4 Medicines Defect Information: Dr. Reddy's Laboratories (UK) Ltd, Finasteride 5 mg Tablets • Class 4 Medicines Defect Information: Advanz Pharma Zapain 30mg/500mg Tablets 	12/02/20	For info	No further action for APC.
<p>Esmya (ulipristal acetate): suspension of the licence due to risk of serious liver injury</p> <p>Contact patients currently taking Esmya for uterine fibroids as soon as possible and advise them to stop their treatment. The licence for Esmya has been suspended to protect public health while a safety review is conducted following a further case of liver injury requiring transplant.</p>	18/03/20	On formulary as RED drug in Chapter 6.4.1.2	Remove from formulary.

<p>Tofacitinib (Xeljanz▼): new measures to minimise risk of venous thromboembolism and of serious and fatal infections Caution should be used in patients with known risk factors for venous thromboembolism in addition to the underlying disease. Patients older than 65 years of age are at an increased risk of serious infections and should be treated with tofacitinib only if there is no alternative treatment.</p>	18/03/20	On formulary as RED drug in chapter 1.5.3. and 10.1.3	Add link to MHRA guidance.
<p>Baricitinib (Olumiant▼): risk of venous thromboembolism Discontinue baricitinib treatment permanently if clinical features of deep vein thrombosis or pulmonary embolism occur. Prescribers are reminded to use caution if using baricitinib in patients with risk factors for deep vein thrombosis or pulmonary embolism in addition to rheumatoid arthritis.</p>	18/03/20	On formulary as RED drug in chapter 10.1.3	Add link to MHRA guidance.
<p>SGLT2 inhibitors: monitor ketones in blood during treatment interruption for surgical procedures or acute serious medical illness SGLT2 inhibitor treatment should be interrupted in patients who are hospitalised for major surgical procedures or acute serious medical illnesses and ketone levels measured, preferably in blood rather than urine. Treatment may be restarted when the ketone values are normal and the patient's condition has stabilised.</p>	18/03/20	On formulary as GREEN drugs in chapter 6.1.2.3	Add link to MHRA guidance.
<p>Benzodiazepines and opioids: reminder of risk of potentially fatal respiratory depression Benzodiazepines and opioids can both cause respiratory depression, which can be fatal if not recognised in time. Only prescribe together if there is no alternative and closely monitor patients for signs of respiratory depression.</p>	18/03/20	On formulary as GREEN drugs in chapter 4.1	Add link to MHRA guidance.
<p>Letters and drug alerts sent to healthcare professionals in February 2020</p> <ul style="list-style-type: none"> • Typhim Vi (Typhoid polysaccharide vaccine): Supply of Standard Export pack • Mepact 4mg (mifamurtide): Potential for filter leakage or malfunction • Xeljanz▼ (tofacitinib): increased risk of venous thromboembolism and increased risk of serious and fatal infections • Class 2 Medicines Recall: Emerade 150 micrograms solution for injection in pre-filled syringe, PL 33616/0013 (EL(20)A/14). 4 March 2020. • Class 2 Medicines recall: Accord-UK Ltd, Gliclazide 40mg Tablets (Northstar Livery), PL 20075/0687, (EL (20)A/08). Issued 13 February 2020. • Class 2 Medicines recall: Medreich PLC, Ranitidine 150mg Tablets, PL 21880/0091, Ranitidine 300mg Tablets, PL 21880/0092 (EL (20)A/05). Issued 3 February 2020. • Company led drug alert – Iohexol solution for injection (350mg/ml and 300mg/ml). Issued 6 February 2020.. • Class 3 FMD Medicines Recall, Beconase Aqueous Nasal Spray, (Beclometasone Dipropionate 50µg), PL 10949/0104, EL (20)A/07. Issued 12 February 2020. 	18/03/20	For info	No further action for APC.

<p><u>Coronavirus (COVID-19): latest guidance for medicines safety</u> Key MHRA advice and guidance issued so far on medicines safety and pharmacovigilance, including on reporting to the Yellow Card Scheme.</p>	27/04/20		Add links to advice on: Ibuprofen and NSAIDs Antihypertensives Chloroquine and hydroxyl--chloroquine
<p><u>Letters and drug alerts sent to healthcare professionals in March 2020</u></p> <ul style="list-style-type: none"> • Esmya 5mg (ulipristal acetate) for uterine fibroids: not to be used during ongoing review of liver injury risk – see Drug Safety Update, March 2020 and Class 2 recall notice • Adoport (tacrolimus) 2mg capsules: limited number of packs with Italian foil • Fennings Paracetamol 120mg/5 ml Oral Suspension (Crescent Pharma Ltd): 200ml pack size on a GSL authorisation; only to be supplied under the supervision of a pharmacist • Ativan 4mg/ml Solution for Injection (Lorazepam): interim supply of Irish stock to mitigate supply disruption • Zentiva Paracetamol 500mg Capsules (pack size 100 capsules) supplied with incorrect information in Patient Information Leaflet 	27/04/20	For info	No further action for APC.
<p><u>Coronavirus (COVID-19): new dedicated Yellow Card reporting site for medicines and medical devices</u> Reporting to the new site will enable the MHRA to rapidly identify new and emerging side effects and medical device incidents in COVID-19 treatment, including side effects for medicines taken by patients to manage long-term or pre-existing conditions.</p>	21/05/20	n/a	No action for formulary but promote in newsletters to prescribers
<p><u>Valproate Pregnancy Prevention Programme: temporary advice for management during coronavirus (COVID-19)</u> Guidance has been published to support initiation of valproate in female patients and for annual review and pregnancy testing during the coronavirus pandemic. See MHRA guidance at gov.uk/guidance/valproate-pregnancy-prevention-programme-temporary-advice-for-management-during-coronavirus-covid-19 The valproate PPP states that patients on valproate who have experienced menarche must have a review at least annually with the prescribing specialist to reassess the need for valproate therapy and consider alternative treatment options. Annual reviews should not be delayed due to the pandemic.</p>	21/05/20	Listed in chapter 4.8, 4.7.4 and 4.2.3	Add link to formulary against relevant drugs.
<p><u>Immunomodulatory drugs and pregnancy prevention: temporary advice for management during coronavirus (COVID-19)</u> Guidance has been published about thalidomide, lenalidomide, and pomalidomide and the use of remote consultations and home pregnancy testing for patients taking them during COVID-19.</p>	21/05/20	Listed in chapter 8.2.4	Add link to formulary against relevant drugs.

<p><u>Letters and drug alerts sent to healthcare professionals in April 2020</u></p> <ul style="list-style-type: none"> • Class 2 Medicines Recall: Emerade 300 micrograms solution for injection in pre-filled syringe, PL 33616/0014 (EL(20)/A/20) – issued 7 April 2020 • Class 2 Medicines Recall: Emerade 500 micrograms solution for injection in pre-filled syringe, PL 33616/0014 (EL(20)/A/20) – issued 18 May 2020 • ReQuip (ropinorole hydrochloride) tablets: important changes to the colour of carton and blister packs • Cyproterone acetate: restrictions in use of due to risk of meningioma • Class 4 Medicines Defect Information: Glaxosmithkline Consumer Healthcare (UK) Trading Limited, various products, EL(20)/A/22. Issued 20 April 2020. Due to a machinery defect with the printing line, a small number of packs may not have the batch number and expiry date printed on the outer cartons. • Class 4 Medicines Defect Information: Levofloxacin 500mg Tablets, PL 00289/1047 EL (20)/A/21. Issued 16 April 2020. The Product Code/GTIN (PC) number found on the listed batches is incorrect. 	21/05/20	For info	No further action for APC.
Requested formulary amendments	BNF Chapter	Reasoning	Recommended action for APC
<p>Flubiprofen</p> <p>Commissioning: CCG, tariff included</p>	10.1.1	<p>The ophthalmology team at STHFT have agreed that oral flubiprofen can be removed from formulary as never used for ophthalmology indications.</p> <p>Was only previously listed on STHFT formulary.</p>	Do not add to formulary
<p>Remdesivir infusion for confirmed COVID-19 infected patients</p> <p>Commissioning: NHSE</p>	18	Approved for the treatment of coronavirus 2019 (COVID-19) as per national DHSC commissioning policy for remdesivir in the treatment of COVID-19.	Added to formulary as RED drug
<p>Triptorelin 22.5mg (Decapeptyl SR®) Injection for precocious puberty</p> <p>Commissioning: CCG, tariff included</p> <p>Approved by STHFT March 2020 D&T for use paediatric endocrinology</p>	6.7.2	<p>Currently the formulary lists the following formulations as approved for use in treating precocious puberty:</p> <ul style="list-style-type: none"> • Gonapeptyl Depot® 3.75mg injection; • Decapeptyl SR®11.25mg injection. 	Add to formulary as AMBER Specialist Initiation as per other formulations of triptorelin for precocious puberty.
New formulary applications	BNF Chapter	Reasoning	Recommended action for APC
Nil this month			

ACTION:

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

13. New Drug Applications

Nil for this meeting.

14. NTAG Update

The following were recommendations from the June 2020 NTAG meeting were circulated for information:

- Voke® Inhaler Nicotine Replacement Therapy for Smoking Cessation
- Lycra Garments for the management of cerebral palsy and other neurological or musculoskeletal conditions
- Infliximab Subcutaneous (Remsima®)
- Verteporfin (Visudyne®) with photo-dynamic therapy for chronic central serous chorioretinopathy
- Vaginal devices for female urinary stress incontinence
- Purewick® female external urinary catheter

It was agreed to update the formulary in line with these recommendations.

The NTAG Workplan June 2020 was also circulated for information.

ACTION:

- **RDTCC to update the online formulary with the approved changes**

15. RMOCC Update

Nil to report this month. RMOCC has not meet since February 2020 due to COVID-19.

14. CDDFT CSTC Update

Nothing to report from last meeting.

15. NTHFT D&T Update

No update available.

16. STHFT D&T Update

Not meet since March 2020. Next D&T meeting is scheduled for September 2020.

It was noted that couple of formulary applications for dietary products were pending and was agreed these should come via FSG/APC as may have implications/impact on prescribing in primary care.

17. Primary Care Prescribing Committee Updates

The County Durham CCG Prescribing Committee Update was circulated for information

The Tees Valley CCG Prescribing Committee Update was circulated for information.

Part 5 – Shared Care and Guidelines (non-Mental Health)

18. VTE Pathway

The need to update current pathways for VTE in light of updated NICE Guidance, NG158: Venous thromboembolic diseases: diagnosis, management and thrombophilia testing published in March 2020 was discussed.

The key changes to NICE guidance are:

- DOACs for active cancer
- Apixiban and Rivaroxaban are both joint first choice anticoagulant choices
- Threshold changes for D-dimer based on age
- Changes to need for cancer follow up for unprovoked DVT

It was noted that whilst there is current pathway in primary care in County Durham, Darlington and South Tees, there is not one in place in HAST.

It was suggested to keep rivaroxaban as the 1st choice locally as this is the DOAC used most locally for VTE and clinicians are more familiar with it as a result. It was also suggested that warfarin plus LMWH should be removed as treatment option for DVT.

It was agreed after discussion to update the existing guidelines in County Durham, Darlington and South Tees, but not to develop a single VTE pathway across County Durham & Tees

Valley at this time. This is because not in a position to develop a single pathway at this time due to other priorities during current COVID-19 pandemic.

ACTION:

- **DR to updated current County Durham & Darlington DVT pathway and support update of current South Tees pathway.**
- **JH to identify representative from CDDFT to support update of County Durham & Darlington DVT pathway.**

19. Asthma and COPD Guidelines – updated

The updated local prescribing guidelines in Adult Asthma, Paediatric Asthma and Chronic Obstructive Pulmonary Disease (COPD) were presented to and approved by the APC for use across County Durham and Tees Valley. These have been developed in consultation with the Respiratory Clinical Advisory Groups in both County Durham and Tees. The Declarations of Interest of Respiratory CAG members were noted but no further actioned required as included several companies that supply inhalers, and none of the companies had a direct influence on the guidelines.

It was noted that North Yorkshire currently follow BTS COPD guidelines rather than GOLD in Harrogate and York localities, and so some work will required outside of APC with regard to cross border issues.

ACTION:

- **RDTC to arrange for approved version to be added to APC pages of NECS website.**
- **AM/CR to speak outside of APC meeting re cross border issues with COPD guidance in North Yorkshire.**

20. Pain Guidelines – updated

A proposal to update and adopt the current Tees Pain Management Guidance for Non-Cancer Pain in Primary Care in County Durham was presented to the APC.

On expiry of previous primary care pain guidelines across the County Durham CCG area, the adoption of existing Tees Valley guidance has been consulted on County Durham primary care, secondary care and CCG. The most significant difference between the prior Durham guidance and the Tees Valley guidance is the maximal daily dosing of morphine, 100mg in Durham and 120mg in Tees Valley. Wording to the affect to allow this to continue has been included within the draft copy. Upon consultation, trigeminal neuralgia will now no longer be covered by a guideline and the suggestion is for a wider consultation and development of a specific guideline to cover this indication. The benefit of the use of adopting this guidance can be seen from the comments by clinicians that have responded to the consultation.

The adoption of one Pain Management Guidance for Non-Cancer Pain in Primary Care covering County Durham and Tees Valley was approved in principal by the APC subject to the following:

- Change title of the guideline to state also covers withdrawal and use of high risk drugs in primary care.
- Consideration given to inclusion of Tramadol MR if advised by pain specialists.
- Inclusion of information on management of codeine non-responders.
- Suggested keep all management of neuropathic pain (including Trigeminal neuralgia, post herpetic neuralgia, and diabetic neuropathy) in this document so all pain guidance in one place.
- Check Zaleplon still exists, if not remove.
- Benzo section page 5 - suggest removing alprazolam and oxazepam, nitrazepam and flurazepam from e.g. sections

It was agreed to ask for these changes to made before final version presented to August 2020

FSG and September 2020 APC for approval

ACTION:

- **RDTC to feedback to Rachel Berry and Mohammed Rafi changed required before final version can be approved by APC.**

Part 5 – Other Items of Business

21. CD&T APC Annual Report 2019/20

A draft annual report for the APC was presented to and approved by the APC subject to the following amendments:

- Inclusion and acknowledgement of North Yorkshire CCG as a stakeholder within in text.
- Inclusion of financial delegated authority limits of APC decision making.

ACTION:

- **RDTC to arrange for approved version to be added to APC pages of NECS website once amendments made and approved via Chair's Action.**

22. Review of CD&T APC Workplan in Light of COVID-19

The APC discussed and reviewed its current workplan in light of Covid-19 to see if anything needs to be added or removed.

Prior to the July 2020 APC members were asked to list the three priorities for their sector/organisation over the next 12-24 months and the responses received were presented to the APC.

The APC consider the following the following themes as suggested in the consultation with APC members:

- Support for changes in care delivery models such as virtual care, shared care protocols, formulary RAG status reviews and care home support.
- New ways of working for APC and its subgroups by formalising some of the changes made to incorporate virtual meetings, and enhanced collaboration with regional networks and colleagues.
- Move to more efficient governance processes supporting faster decision making as seen during the production of local COVID guidance.

ACTION:

- **RDTC to update the APC workplan and circulate to APC members.**

23. Review of CD&T APC Terms of Reference

The APC Terms of Reference are reviewed on annual basis each July. An updated version of the Terms of Reference with suggested changes following consultation with APC members via email was presented to and approved by the APC. This included the need to ensure that meetings remain quorate if attendees need to leave the meeting early, and ensuring this is captured in the minutes.

The updated membership of the APC to reflect recent CCG mergers was also approved.

The APC also discussed the need to communicate the new Terms of Reference to all stakeholder organisations to raise continued awareness of the APC and ensure both clinical and pharmacy representation from each organisation on a regular basis at APC meetings. It was noted in particular that a clinical representative from NTHFT to APC has still not been identified.

ACTION:

- **RDTC to arrange for updated APC Terms of Reference to be added to APC pages of NECS website.**

- **ID to write to NTFHT Medical Director and Chair of D&T to seek a clinical representative to APC.**

24. Aspirin in Pregnancy

The APC was made aware of and discussed current issues around how pregnant patients access supply of aspirin for use during pregnancy to reduce the risk of pre-eclampsia. The latest issues have been raised in relation to STHFT.

There appears to be continued advice given by midwives suggesting that pregnant patients should go to buy aspirin from a community pharmacy to reduce risk of pre-eclampsia. Although this use is common in UK clinical practice aspirin does not have a UK marketing authorisation for this indication. Community pharmacies cannot legally sell aspirin as a pharmacy medicine for prevention of pre-eclampsia in pregnancy in England. Aspirin for this indication must be prescribed. Midwives currently are not legally authorised to prescribe aspirin (and other preventative medicines used in pregnancy). Some GPs seem happy to prescribe for this indication provided they receive adequate communication of need from the obstetric team.

It was agreed to undertake a piece of work to explore the best route of supply for aspirin in pregnancy including looking the use of a PGD or Protocol for midwives to supply.

ACTION:

- **AM to explore the best route of supply for aspirin in pregnancy in Tees and to liaise with CDDFT plus County Durham.**

Part 6 – Standing Items (for information only)

- 25. Formulary Steering Group Minutes – February 2020**
Not yet available.
- 26. TEWV D&T Minutes – January 2020**
For information.
- 27. CDDFT Clinical Standards and Therapeutics Committee Minutes – December 2019**
For information.
- 28. North Tees & Hartlepool Hospitals D&T Minutes – since January 2020**
Not yet available.
- 29. South Tees Hospitals D&T Minutes – March 2020**
For information.
- 30. RDTC Horizon Scanning – March, April, May & June 2020**
For information.
- 31. NE&C CCG Prescribing Forum Minutes – since December 2019**
Not yet available.
- 32. NEAS Medicines Group Minutes – since November 2019**
Not yet available.
- 33. NTAG Minutes - February 2020**
For information.

Chairman's Action

[CDT APC Anticoagulation during Covid-19 - approved 24.4.2020](#)

Approved by Chair's Action due to urgency and published on APC website A copy was also circulated with the APC Agenda.

APC memo - position on the NHSE proposal for DOAC procurement during Covid-19 - final
Approved by Chair's Action due to urgency and circulated to GP practices. A copy was also circulated with the APC Agenda.

CDT APC Self-Monitoring of Blood Glucose Guideline – minor update June 2020
Minor update around safety needles approved by Chair's Action since original version approved at March 2020 APC.

Any Other Business

APC Meetings via Microsoft Teams

It was discussed and agreed that future meetings on the APC would be held via Microsoft Teams rather than in a physical meeting room. This was because of the savings in travel time leading to more productivity before and after meetings for members, and the continued need for meetings for held virtually online in the shorter term due to COVID-19.

Date and time of next meeting:

Thursday 10th September 2020, 9am – 11.30am, virtual meeting via Microsoft Teams tele/videoconference – details to be circulated.