County Durham & Tees Valley
Area Prescribing Committee

County Durham and Tees Valley Area Prescribing Committee

Thursday 11th March 2021
9am – 11.30am
Held Via Microsoft Teams

Present

Name	Job Title	Membership Capacity	Organisation	July 2020	Sep 2020	Nov 2020	Mar 2021
David Russell	GP Prescribing Lead (Darlington)	Clinician	Tees Valley CCG	✓	✓	✓	✓
Angela Dixon	Medicines Optimisation Pharmacist	Pharmacist	Tees Valley CCG	Alastair Monk	✓	✓	✓
Peter Foster	GP Prescribing Lead	Clinician	County Durham CCG	✓ (left at 10.20am)	✓	✓	✓
Kate Huddart	Senior Pharmaceutical Advisor	Pharmacist	County Durham CCG	✓	✓ (Rachel Berry from 10.15am)	✓ (Rachel Berry from item 10)	✓
Tim Rider	GP Prescribing Lead	Clinician	North Yorks CCG		Chris Ranson		
Susan Broughton	HRW Locality Lead Pharmacist	Pharmacist	North Yorks CCG	Chris Ranson	✓	Chris Ranson	Chris Ranson
Rupert Smith	GP Prescribing Lead	Chair of FSG	Tees Valley CCG	✓	✓	✓	✓
Ian Davidson (Chair)	Medical Director	Clinician	County Durham CCG	✓	✓	✓	✓
Janet Walker	Medical Director	Clinician	Tees Valley CCG	✓	Apols	✓	✓
Shafie Kamaruddin	Consultant & Chair of CSTC	Clinician	CDDFT	✓ (left at 10.30am)	✓	✓ (items 3,5,& 25 only)	✓
Jamie Harris	Chief Pharmacist	Pharmacist	CDDFT	✓	✓	✓	✓
		Clinician	NTHFT				
Chris Mallon	Formulary Pharmacist	Pharmacist	NTHFT	Apols		✓	✓
Andy Lloyd	Consultant & Chair of D&T	Clinician	STFT	✓	✓		✓ from item 5
Helen Jones	Chief Pharmacist	Pharmacist	STFT	✓	✓	✓	✓
Baxi Sinha		Clinician	TEWVFT	✓	Apols	✓ (left after Item 12)	✓ (left after Item 25)
Chris Williams	Chief Pharmacist	Pharmacist	TEWVFT	✓	✓	✓	✓
Julie Birch or Tanya Johnston	GP	LMC Rep			Tanya Johnston	Tanya Johnston	
Rob Pitt	Community Pharmacist	LPC Rep – County Durham			✓	✓ (from item 11)	✓
Brent Foster	Community Pharmacist	LPC Rep – Tees		✓			
Claire Jones	Public Health Pharmacist	Public Health Rep	Durham Council	Apols		Apols	Apols
Chris Cunnington - Shore		Service User Rep – County Durham		✓	✓	✓	✓
		Service User Rep - Tees					

Mark Pickering	Chief Finance Officer for Tees Valley CCG	Commissioning & Finance Rep	Tees Valley CCG	✓	Apols	✓ (left after item 11)	Apols
Rosie England	Chief Pharmacist	NEAS	NEAS				
Gavin Mankin	Principal Pharmacist Medicines Management	Professional Secretary	Regional Drug & Therapeutics Centre, Newcastle	✓	✓	✓	✓

In attendance
Conor McCahill – Pharmacist, RDTC – observing
Samuel Durrant - NHSE Management Trainee – observing
Alda Hummelinck – Pharmacist, NECS working with County Durham CCG – observing
Emily Brown – RDTC Admin Support – sharing papers via screen on MS Teams

The meeting was quorate and remained quorate throughout.

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, Mark Pickering

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:
None declared.

3. Minutes and Decision Summary of the Previous APC Meeting Held on 12th November 2020
The minutes were accepted as a true and accurate record.
The decision summary of the November 2020 meeting was accepted as a true and accurate record.

It was brought to the attention of the APC that the vote to approve Slentyo® was not in line with the 75% majority required as per the APC Terms of Reference. This has only just come to light when reviewing the Terms of Reference as an agenda item for the March 2021 APC meeting. The Chair and Professional Secretary acting in good faith at the time believing a simple majority vote as required. It was agreed not to review the decision to approve Slentyo® as 63% of voting members on the day voted to approve, and due to the potential financial impact the decision has now been ratified by County Durham, Tees Valley, and North Yorkshire CCGs.

Note that January 2021 APC meeting was cancelled due to COVID-19 vaccine rollout.

4. Decision Summary for January 2021 Formulary Amendments

For information. Approved via Chair's Action following email consultation with APC members in lieu of January 2021 APC Meeting.

5. Matters Arising Not On the Agenda

Nil.

6. Action Log

Melatonin Slenyto® Formulary Application

Was sent to CCG Executive Committees as above financial threshold of level of delegated authority of APC. Approved by Tees Valley CCG at their February 2021 meeting, and County Durham CCG at their March 2021 meeting. Also approved by North Yorkshire CCG.
The shared care guideline to support this decision will be approved at the March 2021 TEWV D&T and then adopted by other APC stakeholder Trusts. ITEM NOW CLOSED.

CD&T APC Transanal Irrigation Guidelines

Following approval at November 2020 APC now approved via Chair's Action and now added to website. ITEM NOW CLOSED.

Riluzole Shared Care Guideline – reviewed and updated

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

CD&T APC Vitamin D Guideline – reviewed and updated

Now added to website. ITEM NOW CLOSED.

Tapentadol Dose Reduction Guidance for Primary Care

Now added to website. ITEM NOW CLOSED.

Northern England Evaluation and Lipid Intensification guideline

Awaiting final version to add to website.

Shared Care Agreement Across ICS

CD&T responded in support as did Sunderland APC. Response awaited from NoT APC.

Identifying Lead for Updating Local Atrial Fibrillation Guidelines

Still to identify a lead for updating local Atrial Fibrillation Guidelines.

RMOC Liothyronine Guidance

No further update due to COVID-19.

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

Still await updated timescales for NICE updating their guidelines.
NE Prescribing Forum/CCG MO Leads are also preparing an options paper for CCG Finance Committees.

TA607: Rivaroxaban for CAD/PAD

On today's agenda.

Review of CD&T APC Terms of Reference

Chair written to NTFHT Medical Director to seek a clinical representative to APC, and response awaited. Chris Mallon agreed to follow this up within NTHFT – it has been escalated again to their Chief Pharmacist and Medical Director.

CD&D DVT Pathway – updated

Confirmed that this pathway will adopted by Out of Hours teams. ITEM NOW CLOSED.

Hydroxychloroquine SCG

Awaiting final RMOC South Guidance which was out for consultation in Oct 2020. Noted new RCOpth guidance now available as of December 2020 which may help manage capacity. Noted ongoing work within CCGs on this.

7. APC Terms of Reference – updated

The APC discussed the APC Terms of Reference which have been updated to reflect changed in the agreed levels of delegated authority for decision making that the APC as agreed by County Durham CCG and Tees Valley CCG in January/February 2021.

Changes to the wording around voting if one is required to make a decision were also discussed and it was proposed to change from current 75% majority required to simple majority in favour with any vote to reflect a balance of APC membership and stakeholders.

These changes were approved by the APC.

ACTION:

- **RDTC to arrange for approved version to be added to APC pages of NECS website.**

8. Joint working with South Tyneside & Sunderland APC

A paper to seek the views and approval from County Durham & Tees Valley APC and South Tyneside & Sunderland APC on the initial sharing of agendas, decision summaries and minutes between the two groups was presented to the group.

The two APCs in the Central ICP are asked to consider approving the following as initial step:

- To share agenda, annual workplans, minutes and recommendations/decision summary as standing agenda items at each respective APC meeting.
- To agree to the professional secretary of each APC sharing the full APC meeting papers with their counterpart prior to each meeting to aid information sharing and closer collaboration.
- The professional secretaries to be non-voting members of both APCs and to attend both APCs to aid information/decision sharing as the need arises.
- Each APC to update their Terms of Reference to reflect the above.

This proposal was approved by the APC as positive step to avoid postcode prescribing issues and closer collaboration on medicines related issues.

ACTION:

- **RDTC to update the APC Term of Reference to reflect information sharing with South Tyneside & Sunderland APC.**
- **RDTC to arrange for updated version of ToR to be added to APC pages of NECS website.**
- **RDTC to add South Tyneside & Sunderland APC to membership of CD&T APC to receive APC papers**

Part 2 – Mental Health

9. TEWV Drug & Therapeutics Committee Feedback – November 2020 & January 2021

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

It was noted that the work on weight gain and antipsychotics will be brought to APC at a future date.

Part 3 – Formulary Issues

10. Appeals Against Previous APC Decisions

Nil for this meeting.

11. NICE TAs and MHRA Drug Safety Update – December 2020 & January 2021

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
TA663: Venetoclax with obinutuzumab for untreated chronic lymphocytic leukaemia **Commissioning: NHSE** Venetoclax plus obinutuzumab is recommended as an option for untreated chronic lymphocytic leukaemia (CLL) in adults, only if there is a 17p deletion or TP53 mutation, or there is no 17p deletion or TP53 mutation, and fludarabine plus cyclophosphamide and rituximab (FCR), or bendamustine plus rituximab (BR), is unsuitable, and the companies provide the drugs according to the commercial arrangements. Venetoclax plus obinutuzumab is recommended for use within the Cancer Drugs Fund as an option for untreated CLL in adults, only if there is no 17p deletion or TP53 mutation, and FCR or BR is suitable, and the conditions in the managed access agreement for venetoclax plus obinutuzumab are followed.	09/12/20	Listed as RED drug in 8.1.5	Add link to NICE TA.
TA664: Liraglutide for managing overweight and obesity **Commissioning: CCG, tariff included.** Liraglutide is recommended as an option for managing overweight and obesity alongside a reduced-calorie diet and increased physical activity in adults, only if: • they have a body mass index (BMI) of at least 35 kg/m2 (or at least 32.5 kg/m2 for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population) and • they have non-diabetic hyperglycaemia (defined as a haemoglobin A1c level of 42 mmol/mol to 47 mmol/mol [6.0% to 6.4%] or a fasting plasma glucose level of 5.5 mmol/litre to 6.9 mmol/litre) and • they have a high risk of cardiovascular disease based on risk factors such as hypertension and dyslipidaemia and • it is prescribed in secondary care by a specialist multidisciplinary tier 3 weight management service and the company provides it according to the commercial arrangement.	09/12/20	Listed as NOT APPROVED in chapter 4.5 as per previous NTAG recommendation.	Change to a RED drug and add link to formulary to say that only available if CCG commission a tier 3 weight management service.
TA666: Atezolizumab with bevacizumab for treating advanced or unresectable hepatocellular carcinoma **Commissioning: NHSE** Atezolizumab plus bevacizumab is recommended as an option for treating advanced or unresectable hepatocellular carcinoma (HCC) in adults who have not had previous systemic treatment, only if: they have Child-Pugh grade A liver impairment and an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 and the company provides it according to the commercial arrangement.	16/12/20	Listed as RED drug in 8.2.4	Add link to NICE TA.
TA667: Caplacizumab with plasma exchange and immunosuppression for treating acute acquired thrombotic thrombocytopenic purpura **Commissioning: NHSE** Caplacizumab with plasma exchange and immunosuppression is recommended, within its marketing authorisation, as an option for treating an acute episode of acquired thrombotic thrombocytopenic purpura (TTP) in adults, and in young people aged 12 years and over who weigh at least 40 kg. Treatment should be started and supervised by physicians experienced in managing thrombotic microangiopathies. It is recommended only if the company provides caplacizumab according to the commercial arrangement.	16/12/20	Not listed in chapter 8.2.3	Add to formulary as a RED drug and add link to NICE TA.

TA665: Upadacitinib for treating severe rheumatoid arthritis **Commissioning: CCG, tariff excluded** Upadacitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with a combination of conventional disease-modifying antirheumatic drugs (DMARDs), only if disease is severe (a disease activity score [DAS28] of more than 5.1) and the company provides upadacitinib according to the commercial arrangement. Upadacitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to or who cannot have other DMARDs, including at least 1 biological DMARD, only if disease is severe (a DAS28 of more than 5.1) and they cannot have rituximab and the company provides upadacitinib according to the commercial arrangement. Upadacitinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to rituximab and at least 1 biological DMARD, only if disease is severe (a DAS28 of more than 5.1) and the company provides upadacitinib according to the commercial arrangement. Upadacitinib can be used as monotherapy for people who cannot take methotrexate because it is contraindicated or because of intolerance, when the criteria in sections 1.1, 1.2 and 1.3 are met. Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months after starting therapy. After an initial response within 6 months, stop treatment if at least a moderate EULAR response is not maintained. When using the DAS28, healthcare professionals should take into account any physical, psychological, sensory or learning disabilities, or communication difficulties that could affect the responses to the DAS28 and make any adjustments they consider appropriate.	09/12/20	Not listed in chapter 10.1.3	Add as RED drug and link to NICE TA. NICE do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less £9,000 per 100,000 population. This is because the technology is a further treatment option and is available at a similar price to the current treatment options.
TA668: Encorafenib plus cetuximab for previously treated BRAF V600E mutation-positive metastatic colorectal cancer **Commissioning: NHSE** Encorafenib plus cetuximab is recommended, within its marketing authorisation, as an option for treating BRAF V600E mutation-positive metastatic colorectal cancer in adults who have had previous systemic treatment. It is recommended only if the company provides it according to the commercial arrangements.	06/01/21	Listed as RED drug in 8.1.5	Add link to NICE TA.
TA669: Trifluridine–tipiracil for treating metastatic gastric cancer or gastro-oesophageal junction adenocarcinoma after 2 or more therapies **Commissioning: NHSE** Trifluridine–tipiracil is not recommended, within its marketing authorisation, for treating metastatic gastric cancer or gastro-oesophageal junction adenocarcinoma in adults who have had 2 or more systemic treatment regimens.	27/01/21	Listed as RED drug in 8.1.5	Add link to NICE TA.
TA670: Brigatinib for ALK-positive advanced non-small-cell lung cancer that has not been previously treated with an ALK inhibitor **Commissioning: NHSE** Brigatinib is recommended, within its marketing authorisation, as an option for treating anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer (NSCLC) that has not been previously treated with an ALK inhibitor in adults. It is recommended only if the company provides brigatinib according to the commercial arrangement**.**	27/01/21	Listed as RED drug in 8.1.5	Add link to NICE TA.

Drug Safety Advice	Date issued	Current formulary status	Recommended action for APC
Systemic and inhaled fluoroquinolones: small risk of heart valve regurgitation; consider other therapeutic options first in patients at risk Fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients at risk for heart valve regurgitation (incompetence).	17/12/20	UK authorised medicines include ciprofloxacin, levofloxacin, moxifloxacin, and ofloxacin Ciprofloxacin and Ofloxacin GREEN in 05.01.12 Levofloxacin and Moxifloxacin AMBER SI in 05.02.12	Add link to MHRA DSU.
Erythromycin: caution required due to cardiac risks (QT interval prolongation); drug interaction with rivaroxaban Erythromycin has been associated with events secondary to QT interval prolongation such as cardiac arrest and ventricular fibrillation. Erythromycin should not be given to patients with a history of QT interval prolongation or ventricular cardiac arrhythmia, including torsades de pointes, or patients with electrolyte disturbances. A potential drug interaction between rivaroxaban and erythromycin resulting in increased risk of bleeding has also been identified.	17/12/20	GREEN in 05.01.05, with the injection being RED.	Add link to MHRA DSU.
Erythromycin: update on known risk of infantile hypertrophic pyloric stenosis Updates have been made to the magnitude of the known risk of infantile hypertrophic pyloric stenosis following exposure to erythromycin in infancy as a result of new epidemiological data. The risk is particularly increased in the first 14 days after birth. Weigh the benefit of erythromycin therapy in infants against the potential risk of infantile hypertrophic pyloric stenosis.	17/12/20	GREEN in 05.01.05, with the injection being RED.	Add link to MHRA DSU.
Antiepileptic drugs in pregnancy: updated advice following comprehensive safety review A review of the risks of major congenital malformations and of adverse neurodevelopmental outcomes for antiepileptic drugs by the Commission on Human Medicines has confirmed that lamotrigine (Lamictal) and levetiracetam (Keppra) are the safer of the medicines reviewed during pregnancy. This review was initiated in the context of the known harms of valproate in pregnancy, which should only be prescribed to women of childbearing potential if there is a pregnancy prevention programme in place. Clinicians should use this information when discussing treatment options with women with epilepsy at initiation and at routine recommended annual reviews and with women who are planning to become pregnant.	07/01/21	Listed in chapter 4.8	Add link to MHRA DSU.
COVID-19 vaccines (Pfizer/BioNTech and COVID-19 Vaccine AstraZeneca): current advice Recent advice from the MHRA on the COVID-19 vaccines authorised for use in the UK, including advice for people with allergies and for women during pregnancy and breastfeeding.	07/01/21	Listed as GREEN drug in chapter 14.4	Add link to MHRA DSU.
Dimethyl fumarate (Tecfidera): updated advice on the risk of progressive multifocal leukoencephalopathy (PML) associated with mild lymphopenia The monitoring requirements and discontinuation criteria for dimethyl fumarate (Tecfidera) have been strengthened following a small number of reports of progressive multifocal leukoencephalopathy (PML) in patients with mild lymphopenia. Continue to monitor lymphocyte counts and advise patients to seek urgent medical attention if they experience any symptoms or signs suggestive of PML.	07/01/21	Listed as RED drug in chapter 8.2.4	Add link to MHRA DSU.

Letters and drug alerts sent to healthcare professionals in November 2020 A summary of letters and drug alerts recently sent to healthcare professionals. • Ondexxya (andexanet alfa): avoid use of andexanet prior to heparinization. • Tecfidera (dimethyl fumarate): updated recommendations in the light of cases of progressive multifocal leukoencephalopathy (PML) in the setting of mild lymphopenia. • Gilenya (fingolimod): updated recommendations to minimise the risk of drug-induced liver injury (DILI). • Rozlytrek (entrectinib) 100mg and 200mg capsules: missing side effect in EU Patient Information Leaflet. • Solu-Medrone (methylprednisolone as sodium succinate) 40mg powder and solvent for solution for injection: change from lactose-containing to a lactose-free formulation; risk of serious allergic reactions if formulations are confused. • Gliolan (5-aminolevulinic acid, 5-ALA): what to do in case of delayed surgery and information on fluorescence in non-high-grade glioma. • Propofol 10mg/ml (1%) emulsion for injection/infusion: batches with deactivated data in European Medicines Verification System (EMVS). • Midazolam maleate (Epistatus 10mg in 1ml oromucosal solution, multidose bottle), unlicensed, emergency use medication for prolonged, acute, convulsive seizures: potential risk of incorrectly engaged child-resistant container closures • Class 4 Medicines Defect Information, Kolanticon Gel 200ml, (PL 17509/0084), EL (20) A/51. Issued 9 November 2020. • Class 2 Medicines Recall, medac GmbH (T/A medac Pharma LLP) Sodiofolin 50mg/ml Solution for Injection 100mg/2ml, PL 11587/0005, EL (20) A/52. Issued 11 November 2020. • Class 2 Medicines Recall, Mylan UK Healthcare Ltd, Ancotil 2.5 g/250 ml Solution for Infusion, PL 46302/0116, EL (20) A/53. Issued 12 November 2020. • Class 2 Medicines Recall: Kyowa Kirin Limited, Abstral 200 microgram sublingual tablets, EL (20)A/54. Issued 25 November 2020. • Class 2 Medicines Recall: Kent Pharmaceuticals Ltd, Betahistine dihydrochloride 8mg and 16mg Tablets, EL (20)A/55. Issued 26 November 2020. • Class 2 Medicines Recall: Aventis Pharma Limited (t/a Sanofi), Largactil 50mg/2ml Solution for Injection, EL (20)A/56. Issued 26 November 2020.	17/12/20	For info.	For info.
Fingolimod (Gilenya▼): updated advice about the risks of serious liver injury and herpes meningoencephalitis Liver monitoring requirements and discontinuation criteria for fingolimod have been updated following reports of serious liver injury. Fatal cases of encephalitis and meningitis caused by herpes simplex and varicella zoster viruses have also been reported during treatment. Advise patients to seek urgent medical attention if they develop any clinical features of liver dysfunction or meningoencephalitis. Discontinue fingolimod if significant hepatic injury or herpes meningoencephalitis is confirmed.	07/01/21	Listed as RED drug in chapter 8.2.4	Add link to MHRA DSU.
SSRI/SNRI antidepressant medicines: small increased risk of postpartum haemorrhage when used in the month before delivery SSRIs and SNRIs are known to increase bleeding risks due to their effect on platelet function. Data from observational studies suggest that the use of SSRI/SNRI antidepressants during the month before delivery may result in a small increased risk of postpartum haemorrhage. Prescribers should consider this risk in the context of an individual patient's bleeding and thrombotic risk assessment during the peripartum period and the benefits of antidepressants for the patient's mental health during this time.	07/01/21	Listed as GREEN drugs in chapter 5.3	Add link to MHRA DSU. Also check if UKTIS will be updating their information on SSRIs and pregnancy.

Aminoglycosides (gentamicin, amikacin, tobramycin, and neomycin): increased risk of deafness in patients with mitochondrial mutations Evidence suggests an increased risk of aminoglycoside-associated ototoxicity in patients with mitochondrial mutations, including cases in which the patient's aminoglycoside serum levels were within the recommended range. These mitochondrial mutations are rare and penetrance is uncertain. Genetic testing should not delay urgently needed aminoglycoside treatment but may be considered, especially before the start of recurrent or long-term treatment.	07/01/21	Listed as RED drugs in chapter 5.1.4	Add link to MHRA DSU.
Letters and drug alerts sent to healthcare professionals in December 2020 A summary of letters and drug alerts recently sent to healthcare professionals. • Systemic and inhaled fluoroquinolones: risk of heart valve regurgitation/incompetence • Epclusa▼ 200 mg/50 mg film-coated tablets (sofosbuvir/velpatasvir): supply of Irish product • Lorazepam (Ativan 4mg/ml): temporary supply of a different presentation and changes to the instructions • Briviact (Brivaracetam 10mg/ml) Oral Solution: Bottles with narrow neck diameter • HyQvia▼ (human normal immunoglobulin and recombinant human hyaluronidase): crimping defect in hyaluronidase vial • Zerbaxa (ceftolozane/tazobactam) 1g/0.5g powder for concentrate for solution for infusion: global recall of product • Class 3 Medicines Recall: Lupin Healthcare (UK) Limited, Simvador 10mg, 20mg and 40mg Tablets, EL (20)A/57. Issued 3 December 2020. • Class 4 Medicines Defect Information: Generics [UK] Limited t/a Mylan, EL(20)A/58. Issued 14 December 2020. • Class 4 Medicines Defect Information, Co-Careldopa 25mg/100mg tablets, (PL 20242/0028), EL (20)A/59. Issued 15 December 2020. • Class 2 Medicines Recall: Merck Sharp & Dohme Limited, Zerbaxa 1g/0.5g Powder for Concentrate for Solution for Infusion, EL (20)A/60. Issued 16 December 2020. • Company led drug alert: Sodium chloride 0.9% Solution for injection (PL 08828/0178), EL (20)A/04. Issued 18 December 2020. • Class 2 Medicines Recall, medac GmbH (T/A medac Pharma LLP) Sodiofolin 50mg/ml Solution for Injection 100mg/2ml, PL 11587/0005, EL (20) A/61. Issued 29 December 2020.	07/01/21	For info.	For info.
Requested formulary amendments	**BNF Chapter**	**Reasoning**	**Recommended action for APC**
Fexofenadine 120mg tablets **Commissioning: CCG, in tariff**	3.4.1	Changed from POM to OTC	Decision deferred to confirm available OTC & price.
Nebulised Aztreonam lysine (Cayston®) 75 mg powder and solvent for nebuliser solution **Commissioning: NHSE**	5.1.2.3	Is recommended for third-line use in the following subpopulation within its licensed indication: for suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis aged six years and older. Request approved by Jan 2021 STHFT D&T.	Add to formulary as RED drug.

Dolutegravir 50mg/ Lamivudine 300mg FDC tablets (Dovato) **Commissioning: NHSE**	5.3.1	NICE approved for HIV and request approved by Jan 2021 STHFT D&T.	Add to formulary as RED drug.
Dolutegravir 50mg/ Rilpivirine 25mg FDC tablets (Juluca) **Commissioning: NHSE**	5.3.1	For HIV. Request approved by Jan 2021 STHFT D&T. Discussion in a local MDT will be required prior to starting on this medication.	Add to formulary as RED drug.
Phenol In Glycerol 5% W/V **Intrathecal Neurolysis for Cancer pain – for palliative nerve block.** **Commissioning: CCG, tariff included** Intrathecal chemical neurolysis with Phenol is a neuro-destructive technique to provide saddle anesthesia for perineal/pelvic pain, in patients unresponsive to pharmacological therapy or not amenable to surgical treatment. Its use has been advocated in patients with terminal illness with a short life expectancy of less than a year.	18	At the moment STHFT have absolute alcohol, phenol in aqueous solution or phenol in almond oil available: Absolute alcohol can't be used for intrathecal neurolysis as it's very painful to inject. It is hypobaric to cerebrospinal fluid, which will make it spread to wider area than intended. Phenol in Glycerol is hyperbaric to cerebrospinal fluid (CSF), and settles down in the sacral nerves area It tends to diffuse more slowly out of the solution causing a more targeted destruction compared to alcohol or phenol in aqueous solution. Phenol in almond oil is not suitable for intrathecal use. Only concern was safety around storage as it would need to be kept separate from the aqueous solution.	Add to formulary as RED drug.
Teriparatide for osteoporosis in men **Commissioning: NHSE**	6.6.1	Approve for addition to the formulary as per Interim Clinical Commissioning Policy Statement: Teriparatide for Osteoporosis in Men (Adults). NHS England Reference: 201101P	Add to formulary as RED drug.
Dapsone for Dermatology Indications **Commissioning: CCG, in tariff**	5.1.10	Feel it meets the criteria of AMBER SHARED CARE to give GPs more information and will ensure care can be handed over for all patients. A SCG has been drafted by STHFT to support this.	Change from AMBER SI to AMBER share care.

Those NICE TAs and decisions with a potential financial impact above the delegated authority limit of the APC will be sent to the CCG Executive meeting for ratification – noted that none fall above this limit this month.

ACTION:

- **RDTC to update the online formulary with the approved changes.**
- **RDTC to confirm if UKTIS updating their information to reflect MHRA DSU on SSRI/SNRI antidepressant medicines: small increased risk of postpartum haemorrhage when used in the month before delivery.**
- **CW to check advice from TEWV perinatal team re MHRA DSU on SSRI/SNRI antidepressant medicines: small increased risk of postpartum haemorrhage when**

used in the month before delivery.

- **RDTC to confirm price and availability Fexofenadine 120mg OTC preparation before final decision on formulary annotation taken.**

12. New Drug Applications

Nil this month – all included in formulary amendments paper.

13. NTAG Update

The APC noted the following new recommendations following the December 2020 NTAG meeting and agreed that the formulary would reflect the NTAG recommendation:

- Solriamfetol for obstructive sleep apnoea in adults
- Solriamfetol for narcolepsy in adults
- Teriparatide Biosimilar
- Dupilumab and Omalizumab for chronic rhinosinusitis with nasal polyps

The APC noted the following reviewed recommendations following the December 2020 NTAG meeting:

- Stand-alone minimally invasive surgical bipolar radiofrequency ablation for atrial fibrillation – reviewed and no changes made.
- Daily vs on-demand PDE-5 inhibitors for management of erectile dysfunction following treatment for prostate cancer – reviewed and no changes made.

The APC also received the December 2020 NTAG Workplan for information.

14. RMOC Update

The APC noted that the RMOC committees have still not met again following a pause due to COVID-19.

15. CDDFT CSTC Update

Nothing to report from last meeting except have approved updated internal opioid misuse guidelines.

16. NTHFT D&T Update

Last meeting was January 2021. Still trying to get more consultant representation at their D&T and APC. Also looking at lidocaine patches, particularly use in orthopaedics.

ACTION:

- **JH to share with CM work done on controlling use of lidocaine patches at CDDFT.**

17. STHFT D&T Update

March 2021 meeting cancelled. Next meeting May 2021.

18. Primary Care Prescribing Committee Updates

Verbal updates were given. Meetings to resume in April 2021.

Part 4 – Shared Care and Guidelines (non-Mental Health)

19. APC Drug Monitoring Recommendations – reviewed and updated

The final version of the reviewed CD&T APC Monitoring Recommendations following comments received at the November 2020 APC was presented to and approved by the APC subject to the following clarifications:

- Warfarin – confirming usual max interval for monitoring if patient got a heart valve
- Spironolactone – confirming is the stated monitoring is for hypertension as well as for heart failure patients.

The APC also agreed to consider adopting the SPS drug monitoring guideline instead of this local guidance once it has been upgraded into a more interactive user friendly platform, due April 2021.

ACTION:

- **RDTC to confirm usual max interval for INR monitoring if patient got a heart valve and make any necessary change to document prior to publication.**
- **RDTC to confirm if the stated monitoring for spironolactone is for hypertension as well as for heart failure patients and make any necessary change to document prior to publication.**
- **FSG to review RAG status for spironolactone in hypertension.**
- **RDTC to arrange for approved version to be added to APC pages of NECS website.**

20. SGLT2 inhibitors Amputation risk - Northern Foot Care Network Recommendations

APC asked to help in cascading this information, and its key recommendations on behalf of the Northern England Diabetes Footcare Network widely throughout its stakeholder Trusts and CCGs.

ACTION:

- **RDTC to arrange for approved version to be added to APC pages of NECS website.**
- **Stakeholders to disseminate within their own organisations**

21. Regional Gender Dysphoria Guidelines – reviewed & updated

In attendance:
Helen Seymour, Senior Medicines Optimisation Pharmacist NECS
Dr Ewa Young, Consultant in Gender Dysphoria, Northern Region Gender Dysphoria Service

The final draft of the updated Regional Gender Dysphoria guideline was presented to the APC and approved. These guidelines are long overdue review.
The FSG previously reviewed and commented on a draft in December 2020, and agreed was a very useful document for primary care.
The APC agreed that very comprehensive guide which will be a good resource for primary care, and will address some of the concerns of GPs/LMC around prescribing for gender dysphoria.

ACTION:

- **RDTC to arrange for approved version to be added to APC pages of NECS website.**

22. CD&T APC Patient Decision Aids Resource

This document originally produced in Sept 2016 and updated in January 2019 is now due for review. The APC approved the updated document to go on the APC website highlighting the availability of various Patient Decision Aids.

ACTION:

- **RDTC to arrange for approved version to be added to APC pages of NECS website.**

23. Dapsone Shared Care Guideline

The Feb 2021 FSG meeting agreed to recommend to APC changing Dapsone to an AMBER SHARED CARE drug on the formulary and approved the proposed shared care guideline subject to couple of changes. The APC approved both recommendations subject to clarification in the shared care guideline of the timeframe to monitor any change/trend in Haemoglobin over.

ACTION:

- **RDTC to confirm with STHFT re timeframe for any change in Haemoglobin that may give cause for concern and need for action.**
- **RDTC to arrange for approved version to be added to APC pages of NECS website.**

24. Riluzole Shared Care Guideline – reviewed and updated

A final version of the reviewed and updated Riluzole Shared Care Guideline following comments received at the November 2020 APC was presented to and approved by the APC.

ACTION:

- **RDTC to arrange for approved version to be added to APC pages of NECS website.**

25. Tees Ciclosporin Shared Care Guideline

The updated Tees Ciclosporin was approved by the STHFT at their November 2020 meeting It was updated to include dermatology use as well as rheumatology use. At the same time it appears changes were made to some of the monitoring requirements (e.g. WCC) to what rheumatology followed previously at STHFT.

Subsequently it came to the Dec 2020 Formulary Subgroup and it was agreed to recommend approval to APC for use in Tees. When preparing it go to the next APC meeting RDTC noticed in the Adverse Events table there is not anything in there about changes in WCC, neutrophils or elevated blood glucose and this would normally be there. This information was in the adverse effects table for the current rheumatology ciclosporin SCG on the NECS website. This would be a change compared to current rheumatology shared care guideline in Tees. The updated Tees guideline does still recommend ongoing FBC monitoring by GPs but gives not further information on cut offs for abnormal results. BAD guidelines do not include recommendations or parameters for going FBC/glucose monitoring but BSR guidelines do. This was queried and an explanation has to this change has been received from Dr Carmichael at STHFT.

Tees Valley CCG representatives confirmed that were happy this explanation and the changes made. This is subject to some additional wording being added to adverse events section on need to monitor for trends in WCC and investigate cause of any changes.

The APC therefore approved this Ciclosporin SCG for use in Tees Valley, noting a separate SCG exists in County Durham, until ICS level DMARD shared care guidelines are developed.

ACTION:

- **JW/AD to provide suitable wording to be added to adverse events section on need to monitor for trends in WCC and investigate cause of any changes.**
- **RDTC to arrange for approved version to be added to APC pages of NECS website.**

Part 5 – Other Items of Business

26. Rivaroxaban in Preventing atherothrombotic events in people with Coronary or Peripheral Artery Disease (CAD/PAD)

Following the addition to the formulary of rivaroxaban for this indication following the NICE TA in October 2017 ongoing issues remain in primary care locally around implementation of this guidance and how to identify historic patients. It was thought that regional cardiologist were going to produce some guidance but this appears not to be the case.

The cardiac network are not developing local guideline to support implementation of this NICE TA. Cardiologists also expect most patients to be initiated in primary care as they are patients on disease registers rather than under active review by a cardiologist, and are not asking GPs to refer any patient to a cardiologist to initiate treatment.

The RDTC have checked to see how other APCs are implementing this NICE TA and what guidance/supporting they have (if any) for GPs. The other document found on the internet that

may be of use is a checklist for initiation from Coventry & Warwickshire APC which was shared with APC members.
Discussion took place on local implementation including in the diabetes population. It was agreed that a small working group was required to take this forward and advice would sought from local experts

ACTION:

- **SK to set up small task and finish group to look at implementation of NICE TA for Rivaroxaban in Preventing atherothrombotic events in people with Coronary or Peripheral Artery Disease (CAD/PAD).**
- **SK to develop a holding statement for primary care.**

27. Hydroxychloroquine and Chloroquine Retinopathy - New RCOpth guideline Dec 2020

The APC discussed the discussed the impact locally of new RCOpth guideline Dec 2020 on Hydroxychloroquine and Chloroquine Retinopathy. The Royal College of Ophthalmologists have updated their guidance which is stating that baseline test no longer required but a risk assessment at initiation to whether high or low risk. Low risk monitoring is assessed at 5 years then annually and high risk every year. It states now that this does not necessarily need to be done by hospital eye department and leaves open to other community models.
Update RMOC guidance is still awaited following the consultation before Christmas.
The APC noted that discussions around commissioning of the required eye monitoring are ongoing in CCGs.

28. NPSA Alert - Steroid Emergency Card to support early recognition and treatment of adrenal crisis in adults

The APC noted that the actions being undertaken in primary care by CCG Medicines Optimisation Teams to ensure compliance with the NPSA Alert by the required deadline of 13th May 2021.

29. Transfer of AMBER no share care drugs to primary care

The FSG in November 2020 discussed and agreed to propose to the APC some criteria that needs to be included in the transfer of prescribing request from secondary care to primary for Amber Specialist Initiated drugs.
The issue has been raised in response to the step down of denosumab from shared care to amber no shared care but would seem sensible for all drugs in the amber no shared care category.
The following suggested criteria was proposed and agreed by the FSG:
Treatment of X was started on [insert date started] [insert dose].
Baseline investigation and monitoring have been completed and were satisfactory
The risks and benefits of treatment have been explained to the patient.
Please undertake monitoring and treatment from [insert date depending on how much supply has been given]
The next blood monitoring is due on ……
Please continue to monitor this drug in line with the SPC /Local drug monitoring guidance.
I have arranged a follow up with this patient in the following timescale xxxxx.or delete as appropriate.
It was discussed and agreed that this wording represents best practice for Trusts and their prescribers to include in their letters to primary care, but are not really enforceable in practice.

30. North Yorkshire Treatment guidance for uncomplicated hypertension

The proposal to roll out treatment guidance for uncomplicated hypertension that was developed by West Yorkshire and Harrogate Health Hearts programme across North Yorkshire was presented to the APC for information.
The APC noted the potential merits of this guidance and its difference to NICE.
County Durham plus Tees Valley CCG will have internal discussions about possibly adopting something similar.

ACTION:

- **County Durham plus Tees Valley CCG will have internal discussions about possibly adopting something similar to North Yorkshire Treatment guidance for uncomplicated hypertension.**

Part 6 – Standing Items (for information only)

31. Formulary Steering Group Minutes – October & December 2020
For information.

32. TEWV D&T Minutes – November 2020
For information.

33. CDDFT Clinical Standards and Therapeutics Committee Minutes – since June 2020
Not yet available.

34. North Tees & Hartlepool Hospitals D&T Minutes – since September 2020
For circulation post meeting.

35. South Tees Hospitals D&T Minutes – November 2020 & January 2021
For information.

36. RDTC Horizon Scanning – December 2020, January 2021 & February 2021
For information.

37. NTAG Minutes – September 2020
For information.

38. NE&C CCG Prescribing Forum Minutes – January 2021
For information.

39. NEAS Medicines Group Minutes – since November 2019
Not yet available.

Chairman's Action

- CD&T APC Transanal Irrigation Guidelines - final version approved via Chair's Action.
- CD&D/CDDFT Cinacalet Shared Care Guideline – reviewed and updated version approved via Chair's Action.
- TEWV Lithium, Methylphenidate, Atomoxetine and Melatonin Shared Care Guidelines – approved via Chair's Action following email consultation with APC members in lieu of January 2021 APC Meeting.
- January 2021 Formulary Amendments - approved via Chair's Action following email consultation with APC members in lieu of January 2021 APC Meeting.

Any Other Business
Nil

Date and time of next meeting:
Thursday 13th May 2021, 9am – 11.30am, virtual meeting via Microsoft Teams tele/videoconference – details to be circulated.