NHS

County Durham & Tees Valley
Area Prescribing Committee

County Durham and Tees Valley Area Prescribing Committee

Thursday 9th January 2020
9am – 11.30am
Board Room, West Park Hospital, Darlington, DL2 2TS

Present

Name	Job Title	Membership Capacity	Organisation	July 2019	Sep 2019	Nov 2019	Jan 2020
David Russell	GP Prescribing Lead	Clinician	Darlington CCG	✓	✓	✓	✓
Deborah Giles	Medicines Optimisation Pharmacist	Pharmacist	Darlington CCG	Dan Newsome	✓		
Peter Foster	GP Prescribing Lead	Clinician	DDES CCG	✓	✓	✓	✓
Kate Huddart	Senior Pharmaceutical Advisor	Pharmacist	DDES CCG	✓	✓	✓	✓
Mark Duggleby	GP	Clinician	HRW CCG				
Susan Broughton	HRW CCG Lead Pharmacist: Planning and Delivery	Pharmacist	HRW CCG	Ken Latta	✓	✓	✓
Rupert Smith	GP Prescribing Lead	Clinician & Chair of FSG	HAST CCG	Apols	Apols	✓	✓
Michaela Connolly	Clinical Pharmacist	Pharmacist	HAST CCG	✓	Angela Dixon	Apols	Apols
Ian Davidson (Chair)	Medical Director	Clinician	N Durham CCG	✓	✓	✓	✓
Joan Sutherland	Medicines Optimisation Lead	Pharmacist	N Durham CCG	✓	✓	✓	✓
Janet Walker	Medical Director	Clinician	Tees CCGs	A	✓	✓	✓
Alastair Monk	Medicines Optimisation Pharmacist	Pharmacist	S Tees CCG	✓	✓		
Shafie Kamaruddin	Consultant & Chair of CSTC	Clinician	CDDFT	✓	✓	✓	
Jamie Harris	Chief Pharmacist	Pharmacist	CDDFT	✓	Bev Walton	✓	✓
		Clinician	NTHFT				
Chris Mallon	Formulary Pharmacist	Pharmacist	NTHFT	✓	✓	✓	✓
		Clinician	STFT				
Helen Jones	Chief Pharmacist	Pharmacist	STFT	✓	✓	✓	✓
Baxi Sinha		Clinician	TEWVFT	✓	Kath Currah	✓	✓
Chris Williams	Chief Pharmacist	Pharmacist	TEWVFT	✓	Ruth Head	✓	✓
Julie Birch or Tanya Johnston	GP	LMC Rep		✓ TJ	✓ TJ	✓ JB	Apols
Rob Pitt	Community Pharmacist	LPC Rep – County Durham		✓	Apols	✓	✓
Brent Foster	Community Pharmacist	LPC Rep – Tees		Apols	✓	✓	Apols
Claire Jones	Public Health Pharmacist	Public Health Rep	Durham Council	✓	Apols	✓	✓
Chris Cunnington - Shore		Service User Rep – County Durham		✓	Brewis Henderson	Apols	Brewis Henderson

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

In attendance
Nil.

The meeting was quorate.

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

Part 1

1. Apologies for Absence:
Chris Cunnington-Shore, Brent Foster, Michaela Connolly, Julie Birch, Tanya Johnston

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 11: Susan Broughton is a NICE Medicines and Prescribing Associate – agreed as this is a general role could participate in discussion and local decision-making around implementing NICE TAs and guidance.

Item 12: Budesonide (Cortiment®) – Jamie Harris participated in a manufacturer advisory board – it was agreed could not participate in the discussion or decision making on this formulary application.

3. Minutes and Decision Summary of the Previous APC Meeting Held on 14th November 2019
The minutes were accepted as a true and accurate record with some minor amendments to job titles.
The decision summary of the November 2019 meeting was accepted as a true and accurate record.

4. Matters Arising Not On the Agenda

Nil.

5. Action Log

Draft Formulary Application Form

RDTC have circulated and arranged for approved Formulary Application Form to be added APC pages of NECS website. ITEM NOW CLOSED.

Work is underway to update form to expand the financial impact section for primary care. Once complete the updated form will be brought back to APC for approval.

Ketamine in Palliative Care in County Durham

Chair fed back to Dr Morgan the APC decision not to approve. ITEM NOW CLOSED.

Stoma Accessories Guideline

The approved Stoma Accessories Guideline is in the process of being added APC pages of NECS website. ITEM NOW CLOSED.

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

The algorithm is currently being discussed with the Tees diabetes team with a view to adopting across the APC patch.

The financial model for the new guideline has been to the CCG Central Management Group for consideration and they deferred a decision pending further modelling around impact on outcomes in relation to increased upfront drug costs. This may be looked at regionally via NTAG and further discussions on this are ongoing.

Development of APC Workplan

On today's agenda.

Testosterone

Draft a guideline to support the GREEN+ status for testosterone when used for licensed indications is currently in development and will now be picked by NECS MP team via the APC workplan.

Declarations of Interest Policy

Forms circulated. A few remain outstanding and have been chased up by the RDTC.

RMOC Liothyronine Guidance

Was discussed at Oct 2019 meeting of NE Endocrine Network. Looking at regional approach to implementation and review of T3 patients as part of a StR's ST3-5 project in New Year. Also exploring a single consultant in each unit being the single point of contact for T3 cases to improve consistency of care – no further update available.

Cardiology Formulary

On today's agenda.

County Durham and Tees Valley APC Position Statement on Prescribing in Persistent Pain

On today's agenda.

Part 2 – Items Carried Over from Nov 2019 APC

6. Opioid Statement

The comments received on the draft APC position statement on the prescribing of opioids and gabapentinoids persistent pain were reviewed and discussed by the APC. The position statement has been adapted from one that was originally developed by South Tyneside and Sunderland APC.

All stakeholders understand the reasoning behind issuing this statement and the following suggested changes were made based on the comments received to date:

- Remove periodic dose tapering from last paragraph
- 1st box – add in do not initiate in new patients and review use in existing patients

- 2nd paragraph should be changed to soften and state that strategies to reduce the dose should be discussed with the patient with a view to stopping instead of just stopping.
- Add in this is a regional aspiration to reduce the use of opioids and gabapentinoids.

It was agreed further consultation with stakeholders on the final statement with the suggested changes was required before the end of January 2020 and then it would be approved by Chair's Action.

ACTION:

- **KH to update statement with suggested changes and circulate to stakeholders for final comments by the end of January 2020 and then it will be approved by Chair's Action.**

7. APC Workplan

The topics proposed for inclusion the APC workplan for the next 12 months were approved by the APC with the addition of the review of local asthma guidelines to include new information around the use of carbon neutral inhalers.

ACTION:

- **RDTC to work with identified leads to each topic to add information around timescale for work and then circulate/publish final workplan.**

8. Cardiology Formulary

The APC agreed that this document produced by STHFT looks like a useful document for both primary and secondary care subject to some minor modifications. Members were asked to submit any suggested changes to John Stapleton at STHFT. A GP will also be identified to work with John Stapleton to make the document more primary care friendly with guidance added on what is the responsibility of primary care and what is the responsibility of secondary care.

ACTION:

- **RDTC to circulate a word version to APC members for comments.**
- **JW to identify a GP to work with John Stapleton on this document.**

Part 3 – Mental Health

9. TEWV Drug & Therapeutics Committee Feedback – November 2019

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

Part 4 – Formulary Issues

10. Appeals Against Previous APC Decisions

Dymista® (Nov 2019 APC) – following correspondence received from STHFT RDTC are carrying out independent review of all evidence submitted with application and a search for any additional evidence for the FSG to review at their February 2020 meeting. Also plan to meet with the Chair of STHFT D&T about the issues around APC/FSG process that have been raised.

11. NICE TAs and MHRA Drug Safety Update – October & November 2019

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
TA604: Idelalisib for treating refractory follicular lymphoma **Commissioning: NHSE** Not recommended, within its marketing authorisation, for treating follicular lymphoma that has not responded to 2 prior lines of treatment in adults.	02/10/19	On formulary in chapter 8.1.5 as RED drug	Add link to TA604 to chapter 8.1.5
TA605: Xeomin (botulinum neurotoxin type A) for treating chronic sialorrhoea **Commissioning: CCG** Recommended, within its marketing authorisation, as an option for treating chronic sialorrhoea caused by neurological conditions in adults. It is recommended only if the company provides it according to the commercial arrangement.	09/10/19	Botulinum toxin A on formulary in chapters 4 and 13 as a RED drug. No formulary entry for sialorrhoea.	Add to formulary as a RED drug with link to TA605.
TA606: Lanadelumab for preventing recurrent attacks of hereditary angioedema **Commissioning: NHSE, PbRe** Lanadelumab is recommended as an option for preventing recurrent attacks of hereditary angioedema in people aged 12 and older, only if: • they are eligible for preventive C1-esterase inhibitor (C1-INH) treatment in line with NHS England's commissioning policy, that is, they are having 2 or more clinically significant attacks (as defined in the policy) per week over 8 weeks despite oral preventive therapy, or oral therapy is contraindicated or not tolerated • the lowest dosing frequency of lanadelumab is used in line with the summary of product characteristics, that is, when the condition is in a stable, attack-free phase	16/10/19	Not on formulary.	Add to formulary in chapter 3.4.3 as a RED drug, with link to TA606.
TA608: Ibrutinib with rituximab for treating Waldenstrom's macroglobulinaemia (terminated appraisal) **Commissioning: NHSE** NICE is unable to make a recommendation about the use in the NHS of ibrutinib with rituximab for treating Waldenstrom's macroglobulinaemia in adults because Janssen did not provide an evidence submission. The company has confirmed that it does not intend to make a submission for the appraisal because there is unlikely to be sufficient evidence that the technology is a cost-effective use of NHS resources in this population.	30/10/19	On formulary in chapter 8.1.5 as a RED drug.	No further action for this indication as appraisal terminated.
TA609: Ramucirumab for treating unresectable hepatocellular carcinoma after sorafenib (terminated appraisal) **Commissioning: NHSE** NICE is unable to make a recommendation about the use in the NHS of ramucirumab for treating unresectable hepatocellular carcinoma in adults who have had sorafenib, when disease has progressed or sorafenib is not tolerated, because Lilly did not provide an evidence submission. The company has confirmed that it does not intend to make a submission for the appraisal because the technology is unlikely to be a cost-effective use of NHS resources.	30/10/19	On formulary in chapter 8.1.5 as a RED drug.	No further action for this indication as appraisal terminated.

TA607: Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease **Commissioning: CCG** Rivaroxaban plus aspirin is recommended within its marketing authorisation, as an option for preventing atherothrombotic events in adults with coronary artery disease or symptomatic peripheral artery disease who are at high risk of ischaemic events. For people with coronary artery disease, high risk of ischaemic events is defined as one of the following: • aged 65 or over • atherosclerosis in at least 2 vascular territories (such as coronary, cerebrovascular, or peripheral arteries), • 2 or more of the following risk factors: o current smoking o diabetes o kidney dysfunction with an estimated glomerular filtration rate (eGFR) of less than 60 ml/min (note that rivaroxaban is contraindicated if the eGFR is less than 15 ml/min) o heart failure o previous non-lacunar ischaemic stroke. Assess the person's risk of bleeding before considering rivaroxaban. Treatment should only be started after an informed discussion with them about the risks and benefits of rivaroxaban, weighing up the risk of atherothrombotic events against the risk of bleeding. The risks and benefits of continuing treatment with rivaroxaban should be regularly reviewed.	17/10/19	On formulary in chapter 2.8.2 as a GREEN drug	Add as an AMBER Specialist initiation drug for this indication and add link to TA607 to formulary in chapter 2.8.2. It was also agreed to contact cardiology network to see what guidance they have on implementation of this guidance particularly around what to do with historic patients who may be eligible and what tools exist to assess ischaemic risk plus bleeding risk.
TA610: Pentosan polysulfate sodium for treating bladder pain syndrome **Commissioning: CCG** Pentosan polysulfate sodium is recommended as an option for treating bladder pain syndrome with glomerulations or Hunner's lesions in adults with urinary urgency and frequency, and moderate to severe pain, only if: • their condition has not responded to an adequate trial of standard oral treatments • it is not offered in combination with bladder instillations • any previous treatment with bladder instillations was not stopped because of lack of response • it is used in secondary care and the company provides pentosan polysulfate sodium according to the commercial arrangement. This recommendation is not intended to affect treatment with pentosan polysulfate sodium that was started in the NHS before this guidance was published.	13/11/19	On formulary in chapter 7.4.3 as a RED drug.	Add link to TA610 to chapter 7.4.3.
TA611: Rucaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer **Commissioning: NHSE** Rucaparib is recommended for use within the Cancer Drugs Fund as an option for maintenance treatment of relapsed platinum-sensitive high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to platinum-based chemotherapy in adults, only if the conditions in the managed access agreement for rucaparib are followed. This recommendation is not intended to affect treatment with rucaparib that was started in the NHS before this guidance was published.	13/11/19	Not on formulary	Add to formulary in chapter 8.1.5 as a RED drug, with link to TA611.

TA612: Neratinib for extended adjuvant treatment of hormone receptor-positive, HER2-positive early stage breast cancer after adjuvant trastuzumab **Commissioning: NHSE** Neratinib is recommended as an option for the extended adjuvant treatment of hormone receptor-positive HER2-positive early stage breast cancer in adults who completed adjuvant trastuzumab-based therapy less than 1 year ago only if: • trastuzumab is the only HER2-directed adjuvant treatment they have had, and if they had neoadjuvant chemotherapy-based regimens, they still had residual invasive disease in the breast or axilla following the neoadjuvant treatment, and the company provides neratinib according to the commercial arrangement.	20/11/19	Not on formulary	Add to formulary in chapter 8.1.5 as a RED drug, with link to TA612.
TA613: Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema in phakic eyes after an inadequate response to previous therapy **Commissioning: CCG** Fluocinolone acetonide intravitreal implant is not recommended as an option for treating chronic diabetic macular oedema that is insufficiently responsive to available therapies in an eye with a natural lens (phakic eye). This recommendation is not intended to affect treatment with fluocinolone acetonide intravitreal implant that was started in the NHS before this guidance was published.	20/11/19	On formulary in chapter 11.4.1 as a RED drug.	Add link to formulary to say not approved for this indication by NICE.
HST11: Voretigene neparvovec for treating inherited retinal dystrophies caused by RPE65 gene mutations **Commissioning: NHSE** Voretigene neparvovec is recommended, within its marketing authorisation, as an option for treating RPE65-mediated inherited retinal dystrophies in people with vision loss caused by inherited retinal dystrophy from confirmed biallelic RPE65 mutations and who have sufficient viable retinal cells.	09/10/19	Not on formulary.	No further action. Highly specialist. No centres in North-East.
HST12: Cerliponase alfa for treating neuronal ceroid lipofuscinosis type 2 **Commissioning: NHSE** Cerliponase alfa is recommended as an option for treating neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency, only if the conditions in the managed access agreement are followed.	27/11/19	Not on formulary.	No further action. Highly specialist. No centres in North-East.
Drug Safety Advice	**Date issued**	**Current formulary status**	**Recommended action for APC**
Ingenol mebutate gel (Picato▼): increased incidence of skin tumours seen in some clinical studies Advise patients treated with ingenol mebutate gel to be vigilant for new skin lesions and to seek medical advice immediately should any occur. Use with caution in patients with a history of skin cancer.	18/10/19	On formulary in chapter 13.8.1 as a Green Alternative drug	Add link to MHRA advice to chapter 13.8.1
Nivolumab (Opdivo): reports of cytomegalovirus (CMV) gastrointestinal infection or reactivation Patients on nivolumab who present with diarrhoea or other symptoms of colitis, and those who do not respond to steroid treatment for immune-related colitis, should be investigated to exclude other causes, including infections such as CMV.	18/10/19	On formulary in chapter 8.2.4 as a RED drug	Add link to MHRA advice to chapter 8.2.4

Prescribing medicines in renal impairment: using the appropriate estimate of renal function to avoid the risk of adverse drug reactions For most patients and most medicines, estimated Glomerular Filtration Rate (eGFR) is an appropriate measure of renal function for determining dosage adjustments in renal impairment; however, in some circumstances, the Cockcroft-Gault formula should be used to calculate creatinine clearance (CrCl).	18/10/19	For info	No further action
Adrenaline auto-injectors: recent action taken to support safety Healthcare professionals should be aware of alerts and letters issued about adrenaline auto-injectors in September and October 2019. This article provides a summary of recent advice issued to healthcare professionals, including information to provide to patients, to support safe use of adrenaline auto-injectors.	18/10/19	For info	No further action
Letters and drug alerts sent to healthcare professionals in September 2019 • Parenteral nutrition products for neonates and children below 2 years of age: protect from light • Lucentis (ranibizumab) 10 mg/ml pre-filled syringe: plunger on syringe too stiff • Picato▼ (ingenol mebutate): Use with caution in patients with a history of skin cancer – for more information see October 2019 Drug Safety Update article • Jext 150 and 300 micrograms and EpiPen 0.3 mg adrenaline auto-injectors: extended use beyond labelled expiry date for selected lots – for more information see October 2019 Drug Safety Update article • Emerade 150/300/500 micrograms solution for injection in pre-filled pen: complaints of initial failure to activate – for more information see October 2019 Drug Safety Update article • Gilenya ▼ (fingolimod): contraindication in pregnant women and in women of childbearing potential not using effective contraception – for more information see September 2019 Drug Safety Update article • Class 2 Drug Alerts: ranitidine recall, aripiprazole 1mg/mL oral solution recall, bisacodyl 10 mg suppositories recall	18/10/19	For info	No further action
Carfilzomib (Kyprolis▼): risk of reactivation of hepatitis B virus Establish hepatitis B status before initiating carfilzomib and in patients with unknown hepatitis B virus serology who are already being treated with carfilzomib.	21/11/19	On formulary in chapter 8.1.5 as a RED drug.	Add link to MHRA advice to chapter 8.1.5
Yellow fever vaccine: stronger precautions in people with weakened immunity and in those aged 60 years or older The Commission on Human Medicines has issued a series of recommendations to strengthen measures to minimise risk with the yellow fever vaccine (Stamaril) following very rare fatal reactions. Key recommendations include new and updated contraindications and strengthened precautions to protect those with a weakened immune systems (including for people aged 60 years or older) and standardised risk-benefit evaluation procedures across UK yellow fever vaccination centres to ensure that people only receive the vaccine after a thorough risk assessment.	21/11/19	On formulary in chapter 14.4 as a GREEN drug. Only available from designated Yellow Fever Vaccination Centres. Not available on the NHS if being given for travel. May be given via private prescription if required for travel.	Add link to MHRA advice to chapter 14.4.

Letters and drug alerts sent to healthcare professionals in October 2019 • Volibris (ambrisentan): new patient alert card and removal of the controlled distribution system • Quadrivalent Influenza Vaccine (split virion, inactivated): Supply of Standard Export packs Lot T3H244M • Fentanyl 50 micrograms/ml (10ml ampoules): non-UK marketing authorisation number on the label of batch 0112391R • Class 2 drug alerts: ranitidine, Sayana Press 104mg/0.65ml, Nutriflex Omega Plus • Company-led drug alerts: Avonex 30 micrograms/0.5ml and Docetaxel Injection 80mg /8ml • Class 4 Medicines Defect Information: Xonvea 10 mg/10 mg gastro-resistant tablets, Rifadin (rifampicin) 150mg Capsules and Emerade 150, 300 and 500 microgram	21/11/19	For info	No further action

Requested formulary amendments	**BNF Chapter**	**Reasoning**	**Recommended action for APC**
Methadone in palliative care Currently on formulary following harmonisation process as RED with a note Use in pain management should be under the advice of palliative care – this was as per STHFT position. Was GREEN in CD&D previously.	4.7.2	RED status is creating some unnecessary and unintended barriers to appropriate prescribing in palliative care.	Change from RED to AMBER Specialist Initiation/ Recommendation with note that use in pain should be under the advice of palliative care
Renavit Request from renal team at Sunderland to review RED RAG status for Renavit in new harmonised formulary.	9.6.7	In Sunderland classed as GREEN+. STHFT formulary had no RAG status other than Initiated on specialist advice only and for Renal dialysis patients only	Change from RED to AMBER Specialist Initiation/ Recommendation as per Sunderland and NoT formulary. For Renal dialysis patients only
Review of oral Mesalazine brands currently included in formulary Current brands = Asacol, Pentasa and Mezavant XL plus Octasa 400mg. Asacol to be removed from formulary as Octasa has replaced this, those patients on this historically can remain on Asacol but no new patients to be commenced on Asacol.	1.5.1	At present the Octasa 800mg and 1600mg tablets are not available of formulary so if a patient is not willing to take that many tablets, an alternative brand of mesalazine would require to be used to ensure compliance. Salofalk offers the option of sachets for patients unable to swallow tablets/passing whole tablets and is a cheaper option than Pentasa sachets at all doses. Pentasa is required on formulary for patients who have disease that begins in the terminal ileum as is the only formulation to begin release at this point. As Asacol suppositories are no longer available the addition of Salofalk suppositories is necessary as having only one suppository on formulary leads to issues during shortages.	To add all formulations of Salofalk and Octasa to formulary. To remove Asacol from the formulary, whilst patients already on this can remain on Asacol, no new patients should be commenced on asacol The idea is NOT to switch patients already on Octasa to Salofalk but to have Salofalk available for new patients and those struggling with tablets / requiring a sachet formulation. To retain Mezavant XL on formulary.

Lumacaftor/Ivacaftor and Tezacaftor/Ivacaftor for Cystic Fibrosis	3.7	NHSE Clinical Commissioning Urgent Policy Statement: Cystic Fibrosis Modulator Therapies NHS England URN: 190137P	Add to formulary as RED drugs as NHSE commissioned tariff excluded drugs.
Melatonin oral solution 5mg/5ml Propylene glycol and alcohol free	4.1.1	This the current oral liquid recommended in current local shared care guidelines but need to ensure only use if crushing Circadian tablets is not possible. This is only oral solution in the Drug Tariff which is known to be Propylene glycol and alcohol free.	Add to formulary as AMBER Shared Care Drug
Aveeno cream	13.2.1	Zeroveen is considered the same and is less expensive. Aveeno is not used or recommended by dermatology in STHFT or CDDFT.	To remove from formulary
Progesterone pessaries – clarification for formulary status and indications approved for	6.4.1.2	The current formulary entry is unclear.	Confirm formulary status as RED for IVF use and to support the pregnancies of woman who have a history of miscarriage or premature labour as per NICE NG 25.
Apraclonidine 0.5% and 1% eye drops – clarification of formulary status and RAG status	11.8.2.2	Apraclonidine (both strengths) is currently AMBER SI on the new formulary – in light of the differences in licensing for the 2 strengths, CCGs have asked is it possible to add some wording to the formulary to clarify this and also to add info about maximum duration of treatment? Aware that other places have both strengths as AMBER SI for patients with complicated glaucoma when all other options failed to preserve sight on unlicensed basis	Both 0.5% and 1% to remain as AMBER Specialist Initiation when used off-label in complex glaucoma. 0.5% when used as per license prior to laser treatment or surgery to be RED. 1% when used as per license in Theatre = RED
Eflornithine cream – clarification of current RAG status	13.9	Eflornithine is showing as AMBER SI/SR on the new harmonised formulary –it was previously RED in Tees only to be used in combination with laser therapy, and Green+ in CD&D.	Confirm formulary status as RED and to be used only in line with laser therapy.
Torasemide – review of formulary status	2.2.2	Clinical evidence available does not support use over bumetanide or furosemide Given the difference in cost, furosemide seems the better choice at present.	No change. To remain as non-formulary.

Tapentadol – review of formulary status	4.7.2	AMBER specialist initiation on formulary as 3rd line treatment for the relief of severe chronic pain in adults which can be adequately managed only with opioid analgesics AND in whom morphine and oxycodone has failed to provide adequate pain relief or is not tolerated.	No change. For chronic pain team use and inpatient acute pain team use only. Need to ensure patients are followed up by chronic pain team. Chronic pain team at STHFT to prepare a GP information sheet to support appropriate use.
Midodrine for use in postural hypotension	2.7.2	CD&D – no change as Green+ previously. Tees – change from AMBER shared care – no specific monitoring requirements other than BP.	Add to formulary as AMBER specialist initiation for use in postural hypotension
Tolvaptan (Samsca® for non-chemo related SIADH	6.5.2.2	Proposed RED status reflects how the product is currently used in secondary care. This also reflects status in Sunderland and North of Tyne.	Add to formulary as RED For max 10 day course, not for long-term use.
Triptorelin	8.3.4.2	All other LHRH analogues in Tees and CD&D = AMBER SI North of Tyne = Green+ for all Indications including precocious puberty	Add to formulary as Amber Specialist Initiation.
Flumetasone 0.02% with Clioquinol 1% for Otitis Externa	12.1.1	Not included in formulary due supply issues but now available again.	Add to formulary as GREEN
Chloral Hydrate 1g/5mL oral solution	4.1.1	As per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children. STHFT, CDDFT and NTHFT already adopted guidance.	Add to formulary 1g/5ml as RED drug with note that standard strength recommended by RCPCH in children. Remove 500mg/5ml from formulary
Clopidogrel 25mg/5mL oral solution	2.9.2	Do not add to local formulary Not on NoT APC formulary.	Do not add to local formulary as local prescribing data does indicate any use of specials of clopidogrel.
Hydrocortisone 5mg/5mL oral solution	6.3.1	As per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children. STHFT, CDDFT and NTHFT already adopted guidance.	Add this strength to formulary as AMBER SI. Retain 10mg/5ml for now as used NoT.

Omeprazole 20mg/5ml oral solutions	1.3.5	Not listed. Evidence oral liquid not effective in children. Alternatives in Fast tabs or MUPS.	Add this strength to formulary as AMBER SI with note that standard strength recommended by RCPCH in children. To be only for children with narrow bore feeding tubes or those requiring a dose <5mg. Lansoprazole fast tabs or omeprazole MUPS should be used in all other patients.
Phenobarbital (alcohol free) 50mg/5mL oral solution	4.8.1		Replace 20mg/ml with 50mg/5ml strength with note that standard strength recommended by RCPCH in children. (note AMBER SI drug)
Sertraline 50mg/5mL oral solution	4.3.3	No oral liquid currently listed on formulary STHFT, CDDFT and NTHFT already adopted guidance.	Add 50mg/5ml as AMBER SI to formulary with note that standard strength recommended by RCPCH in children.
Sodium chloride 5mmol/mL oral solution	9.2.1	1mmol/ml currently on formulary = licensed product STHFT, CDDFT and NTHFT already adopted guidance.	Add to formulary 5mmol/ml as AMBER SI with note that standard strength recommended by RCPCH in children Retain 1mmol/ml for now as licensed product
Spironolactone 50mg/5mL oral liquid	2.2.3	As per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children.	Add 50mg/5ml as AMBER SI with note standard strength recommended by RCPCH in children. Remove 5mg/5ml, 25mg/5ml and 100mg/5ml from formulary. Retain 10mg/5ml as in NoT formulary
Tacrolimus 5mg/5ml oral liquid	8.2.2	As per NPPG Position Statement: Using Standardised Strengths of Unlicensed Liquid Medicines in Children.	Add 5mg/5ml to formulary as RED with note that standard strength recommended by RCPCH in children

New formulary applications	BNF Chapter	Reasoning	Recommended action for APC
Iron Isomaltoside (Monofer®) injection Iron Sucrose (Venofer), Iron Dextran (Cosmofer) and Ferric Carboxymaltose (Ferrinject) already listed on the formulary as RED drugs.	9.1.1.2	Addition of Monofer may offer some benefits in terms of reduced infusion time and some cost savings to Trusts. Addition of Monofer will allow Trusts a choice of their preferred product.	Add to formulary as RED drug in addition to existing IV iron formulations already included.
Budesonide (Cortiment® 9mg prolonged release tablets in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where 5-ASA treatment is not sufficient.	1.5.2	Budesonide capsules are not licensed for this indication and there is no evidence to support drug delivery to distal colon at the site of disease, and therefore the drug may not be effective in the capsule form for this indication. A licensed treatment should be used where available.	Add to formulary as RED drug as 2nd line treatment – where 5-ASA treatment alone has not induced remission of symptoms, and patients have a clinical need for corticosteroid treatment to induce remission of colitis.
Bictegravir 50mg/ Emtricitabine 200mg/ Tenofovir alafenamide fumarate 25mg Film coated tablets (Biktarvy®) for the treatment of adults infected with human immunodeficiency virus-1 (HIV-1) without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir	5.3.1	NHSE approved and commissioned for this indication.	Add for formulary as a RED drug.
Gardasil 9® suspension for injection Human papillomavirus 9-valent vaccine for Recurrent Laryngeal Papillomatosis (unlicensed indication)	14.4	British Laryngological Association support its use and STHFT D&T support use as RED drug for use in patients with refractory laryngeal papillomatosis requiring frequent surgical procedures to control. Severe cases may need surgery repeating every 6 weeks with a 2 week healing period also affecting the voice. More surgeries means more risk and more long term scarring.	Add to formulary as a RED drug for this indication as per British Laryngological Association guidance.
Zanamivir 10mg/ml solution for infusion (Dectova®) (20ml vials) For the treatment of complicated and potentially life-threatening influenza A or B virus infection in adult and paediatric patients (aged ≥6 months) when: • The patient's influenza virus is known or suspected to be resistant to anti-influenza medicinal products other than zanamivir, and/or • Other anti-viral medicinal products for treatment of influenza, including inhaled zanamivir, are not suitable for the individual patient.	5.3.4	New licensed formulate, previously only free compassionate use unlicensed injection available. Dectova should be used in accordance with official guidance from PHE.	Add for formulary as a RED drug. Would only be used after approval of infectious disease or microbiology

Those NICE TAs with a potential financial impact above the delegated authority limit of the APC will be sent to the CCG Central Management Group meeting for information.

ACTION:

- **RDTC to update the online formulary with the approved changes.**
- **RDTC to contact cardiology network to see what guidance they have on implementation of TA607: Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease, particularly around what to do with**

historic patients who may be eligible and what tools exist to assess ischaemic risk plus bleeding risk.

12. New Drug Applications

- Monofer® injection
- Budesonide (Cortiment®) 9mg MR tabs
- Biktarvy® for the treatment of adults infected with HIV-1
- Gardasail 9® for Recurrent Laryngeal Papillomatosis
- Zanamavir® injection for the treatment of complicated and potentially life-threatening influenza A or B virus

Discussed and approved under Item 11

13. NTAG Update

Nil to report this month.

14. RMOC Update

The following RMOC documents have been published since the November 2019 APC:

RMOC Operating Model 2019

Circulated for information. The APC noted the change in remit for RMOC with regard to the consideration of new drugs which will now be done by NICE.

RMOC Position Statement on Vitamin B Supplementation

The APC agreed to add a link in the formulary to this guidance and that the formulary use of these drugs should reflect this guidance. Information will be added to the formulary about the recommended duration of treatment with thiamine. Formulary already does not recommend use of Vitamin B complex preparations in alcohol use orders, and use in patients with refeeding syndrome is also considered RED locally.

ACTION:

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

RMOC Shared Care Guidance APC Consultation (already shared via email)

APC members were asked to submit any comments on this draft RMOC guidance around Shared Care directly to the RMOC North email address by the end of January 2020.

15. CDDFT CSTC Update

Nothing to report from last meeting.

16. NTHFT D&T Update

Meeting next week.

17. STHFT D&T Update

Verbal update given.

18. Primary Care Prescribing Committee Updates

The County Durham CCGs Prescribing Committee Update was circulated for information
The Tees CCGs Prescribing Committee Update was circulated for information post meeting

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

19. Tees Apomorphine Shared Care Guideline for Approval

The APC approved the Tees Apomorphine SCP updated by neurology team and approved at the South Tees D&T in September 2019. It was noted that the Durham version expires in November 2020 and agreed to harmonise then as draft of updated Tees version had already

been approved by TMGG prior to the APC being formed.,

ACTION:

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

20. Tees Tinzaparin in Obstetrics Shared Care Guideline for Approval

This updated SCG which is only applicable for use in Tees as different commissioning arrangements exist in County Durham & Darlington was approved. It was noted it had been approved at the South Tees D&T in November 2019.

ACTION:

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

21. COPD Guideline

Item deferred until March 2020 APC to allow for consultation with Tees Respiratory Network and consideration of some late changes around use of carbon neutral inhalers.

Part 6 – Other Items of Business

Nil this month.

Part 7 – Standing Items (for information only)

22. Formulary Steering Group Minutes October 2019

For information.

23. TEWV D&T Minutes September 2019

For information.

24. CDDFT Clinical Standards and Therapeutics Committee Minutes - August 2019

For information.

25. North Tees & Hartlepool Hospitals D&T Minutes – November 2019

For information.

26. South Tees Hospitals D&T Minutes – November 2019

For information.

27. RDTC Horizon Scanning – November 2019 & December 2019

For information.

28. NE&C CCG Prescribing Forum Minutes – October 2019

Not yet available.

29. NEAS Medicines Group Minutes - September 2019

For information.

Chairman's Action

Nil.

Any Other Business

<u>Antipsychotic Depot Injections</u>

It was agreed to add sentence to formulary to Risperidone LAI and all the first generation antipsychotic depots that "If the transfer of care was made prior to 11/7/2019 then this drug

was considered as amber specialist initiation and does not need to be referred back to establish shared care. A shared care agreement is required for any transfer from 11/7/2019 onwards".

Format of Update to APC from Formulary Subgroup

The APC supported the new format for presenting new formulary applications to the APC for approval as a summary with the recommendation of the Formulary Subgroup rather than bringing the full application forms themselves. Full application forms and supporting documents together with the rationale for the Formulary Subgroup recommendation would still be brought to APC if the decision was likely to be contentious.

Date and time of next meeting:

Thursday 12th March 2020, 9am – 11.30am, Memorial Hall Board Room, Darlington Memorial Hospital, Darlington