

County Durham & Tees Valley Area Prescribing Committee

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Thursday 13th May 2021 9am – 11.30am Held Via Microsoft Teams

Present

Name	Job Title	Membership Capacity	Organisation	Sep 2020	Nov 2020	Mar 2021	May 2021
David Russell	GP Prescribing Lead (Darlington)	Clinician	Tees Valley CCG	✓	✓	~	√
Angela Dixon	Medicines Optimisation Pharmacist	Pharmacist	Tees Valley CCG	✓	~	~	✓
Peter Foster	GP Prescribing Lead	Clinician	County Durham CCG	√	~	~	~
Kate Huddart	Senior Pharmaceutical Advisor	Pharmacist	County Durham CCG	 ✓ (Rachel Berry from 10.15am) 	 ✓ (Rachel Berry from item 10) 	V	V
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	~	✓ (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) 	Apols
Chris Williams	Chief Pharmacist	Pharmacist	TEWVFT	✓	✓	✓	√
Julie Birch or Tanya Johnston	GP	LMC Rep		Tanya Johnston	Tanya Johnston		Tanya Johnston
Rob Pitt	Community Pharmacist	LPC Rep – County Durham		✓	✓ (from item 11)	√	Apols
Brent Foster	Community Pharmacist	LPC Rep – Tees					
Claire Jones	Public Health Pharmacist	Public Health Rep	Durham Council		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	\checkmark
Rosie England	Chief Pharmacist	NEAS	NEAS				
Gavin Mankin	Principal Pharmacist Medicines Management	Professional Secretary	Regional Drug & Therapeutics Centre, Newcastle	~	~	~	~

In attendance

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:

Chris Mallon, Baxi Sinha, Rob Pitt

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 11th March 2021 The minutes were accepted as a true and accurate record. The decision summary of the March 2021 meeting was accepted as a true and accurate record.

To note the addition of Galcanezumab to the formulary as per the NICE TA in the January 2021 formulary amendments which was above the level of delegated authority of the APC was ratified by the CCG Executive Committees in March 2021.

4. Matters Arising Not On the Agenda Nil.

5. Action Log

<u>APC Terms of Reference – updated</u> Version approved at March 2021 APC now added to website. ITEM NOW CLOSED.

Joint Working With South Tyneside & Sunderland APC

CD&T APC Terms of Reference updated to reflect information sharing with South Tyneside & Sunderland APC, and their APC Secretary now receives the CD&T APC Agenda & Papers. ITEM NOW CLOSED.

MHRA DSU on SSRI/SNRI antidepressant medicines: small increased risk of postpartum haemorrhage when used in the month before delivery

RDTC have confirmed UKTIS are 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. ITEW NOW CLOSED.

CW checked with TEWV perinatal team re MHRA DSU on SSRI/SNRI antidepressant medicines: small increased risk of postpartum haemorrhage when used in the month before delivery and they were not aware of this risk. ITEW NOW CLOSED.

Fexofenadine

RDTC have confirmed that Fenoxfenadine 120mg OTC preparation is not yet available so have not updated the formulary. ITEM NOW CLOSED.

NTHFT Update – Lidocaine patches

JH will share with CM what they have from CDDFT on controlling use of lidocaine patches at CDDFT but most of this work actually done by primary care. ITEM NOW CLOSED.

APC Drug Monitoring Recommendations – reviewed and updated

RDTC have confirmed usual max interval for INR monitoring if patient got a heart value is 6 weeks and made the necessary change to document prior to publication.

RDTC have confirmed the stated monitoring for spironolactone applies only to heart failure patients and have made necessary change to document prior to publication.

FSG have reviewed RAG status for spironolactone in hypertension.

The final approved version has now been added to APC pages of NECS website. ITEM NOW CLOSED.

<u>SGLT2 inhibitors Amputation risk - Northern Foot Care Network Recommendations</u> Actions completed. ITEM NOW CLOSED.

<u>Regional Gender Dysphoria Guidelines – reviewed & updated</u> Awaiting final approved version to add to APC pages of NECS website.

CD&T APC Patient Decision Aids Resource

Approved version now added to APC pages of NECS website. ITEM NOW CLOSED.

Dapsone Shared Care Guideline

RDTC have received feedback from STHFT re timeframe for any change in Haemoglobin that may give cause for concern and need for action, and will now send final version of shared care guideline for Chair's Action prior to publishing final version.

<u>Riluzole Shared Care Guideline – reviewed and updated</u> Approved version now added to APC pages of NECS website. ITEM NOW CLOSED.

Tees Ciclosporin Shared Care Guideline

Suitable wording added to adverse events section on need to monitor for trends in WCC and investigate cause of any changes. Approved version now added to APC pages of NECS website. ITEM NOW CLOSED.

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

No update available on actions from last APC meeting.

North Yorkshire Treatment guidance for uncomplicated hypertension

Both CCGs have discussed adopting this guidance or something similar.

County Durham CCG requested further information relating to outcomes and rationale for difference to NICE for further discussion at the next meeting of their Medicines Optimisation Committee.

Tees Valley CCG does not currently have a local guideline in place for management of hypertension as NICE guidance is available. Adopting the NY guideline would have financial implications in terms of an increase in prescribing spend, however it is anticipated this would be offset by savings in time and resource in general practice by less titration, getting patients to target doses quicker, reducing appointments for monitoring. Concerns were raised regarding moving to a local guideline which would require frequent updates, and it was questioned how useful this would be in addition to the existing NICE guidance. Benefits were discussed including a reduction in consultations for patients switching from ACE to ARB due to cough, and the guidance being useful for healthcare assistants. The group concluded the guidance would not be adopted formally in Tees Valley, however it can be made available as a resource to clinicians if they wish to refer to this to support management of hypertension

It was agreed to close this action as no further action required by APC. ITEM NOW CLOSED.

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, and this is on today's APC agenda for information.

The APC noted CCG Finance Teams have flagged this nationally and with their CCG Executive Committees as an area of high financial risk. Without robust financial modelling CCGs not in a position to approve any updated guidelines financially.

The regional diabetes clinical network are in the process of setting up a working group to try and progress.

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 – no further progress to report.

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 and that RMOC draft shared care template for hydroxychloroquine in development this summer.

Northern England Evaluation and Lipid Intensification guideline Awaiting final version to add to website.

Shared Care Agreement Across ICS On today's agenda.

Identifying Lead for Updating Local Atrial Fibrillation Guidelines

Still to identify a lead for updating local Atrial Fibrillation Guidelines. Note updated NICE AF Guidelines Published 28.4.21. Out of date local patient decision for AF has been removed from APC pages of NECS website.

6. APC Annual Report 2020/21

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

• Sentence re "To work collaboratively with neighbouring APC's to produce consistent

medicines policies throughout the North East and N Cumbria."

• Sentence re type 2 diabetes guidelines and financial risks, and how working to progress this regionally and nationally.

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.

Part 2 – Mental Health

7. TEWV Drug & Therapeutics Committee Feedback – March 2021

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

8. TEWV Citalopram & Escitalopram - maximum dose reductions & ECG algorithm

The previous version of this guidance recommended a baseline ECG in any new patient being considered for treatment with Citalopram or Escitalopram. It has come to attention of TEWV that this is not required in all patients, only in those with pre-existing cardiac disease. The algorithm has been amended accordingly.

The APC approved the amended guidance subject to making clear on flowchart on page 2 who does not need an ECG.

Discussion also took place on the potential need for CCGs to consider doing a patient safety audit to identify historic patients on Citalopram & Escitalopram who may require a ECG check.

ACTION:

• RDTC to arrange for link to approved version to be added to APC pages of NECS website and the formulary.

9. Melatonin SCG updated (now approved and for information)

The updated shared care guideline from TEWV to include Melatonin Slenyto® for its licensed indications only has now been approved at the March 2021 TEWV D&T. Other APC stakeholder acute Trusts have been asked adopt it too.

Part 3 – Formulary Issues

10. Appeals Against Previous APC Decisions Nil for this meeting.

11. NICE TAs and MHRA Drug Safety Update – February 2021 & March 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
TA673: Niraparib for maintenance treatment ofadvanced ovarian, fallopian tube and peritonealcancer after response to first-line platinum-basedchemotherapyCommissioning: NHSENiraparib is recommended for use within the Cancer DrugsFund as an option for maintenance treatment for advanced(FIGO stages 3 and 4) high-grade epithelial ovarian,fallopian tube or primary peritoneal cancer after response tofirst-line platinum-based chemotherapy in adults. It isrecommended only if the conditions in the managed accessagreement for niraparib are followed.	17/02/21	Listed as RED drug in 8.1.5	Add link to NICE TA.

TA671: Mepolizumab for treating severe eosinophilic asthma	03/02/21	RED in 3.4.2 as per NICE TA431: for treating severe	Add link to NICE TA.
 Commissioning: NHSE, tariff excluded Mepolizumab, as an add-on therapy, is recommended as an option for treating severe refractory eosinophilic asthma, only if: it is used for adults who have agreed to and followed the optimised standard treatment plan and the blood eosinophil count has been recorded as 300 cells per microlitre or more and the person has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, or has had continuous oral corticosteroids of at least the equivalent of prednisolone 5 mg per day over the previous 6 months or the blood eosinophil count has been recorded as 400 cells per microlitre or more and the person has had at least 3 exacerbations needing systemic corticosteroids in the previous 12 months (so they are also eligible for either benralizumab or reslizumab). 		refractory eosinophilic asthma. Commissioned by NHS England. TA671 replaces TA431	
At 12 months stop mepolizumab if the asthma has not responded adequately or continue mepolizumab if the asthma has responded adequately and assess response each year. An adequate response is defined as a clinically meaningful reduction in the number of severe exacerbations needing systemic corticosteroids or a clinically significant reduction in continuous oral corticosteroid use while maintaining or improving asthma control.			
TA672: Brolucizumab for treating wet age-relatedmacular degenerationCommissioning: CCG, tariff excludedBrolucizumab is recommended as an option fortreating wet age-related macular degeneration in adults,only if, in the eye to be treated:	03/02/21	NOT APPROVED in 11.8.2.3 as per NTAG	Change to a RED drug and add link to NICE TA as supersedes previous NTAG guidance not to approve.
 the best-corrected visual acuity is between 6/12 and 6/96 there is no permanent structural damage to the central fovea the lesion size is less than or equal to 12 disc areas in 			
 greatest linear dimension and there is recent presumed disease progression (for example, blood vessel growth, as shown by fluorescein angiography, or recent visual acuity changes). It is recommended only if the company provides brolucizumab according to the commercial arrangement. If patients and their clinicians consider brolucizumab to be one of a range of suitable treatments, including aflibercept and ranibizumab, choose the least expensive (taking into account administration costs and commercial arrangements). 			
Only continue brolucizumab in people who maintain an adequate response to therapy. Criteria for stopping should include persistent deterioration in visual acuity and identification of anatomical changes in the retina that indicate inadequate response to therapy.			
TA674: Pembrolizumab for untreated PD-L1- positive, locally advanced or metastatic urothelial cancer when cisplatin is unsuitable (terminated appraisal) Commissioning: NHSE NICE is unable to make a recommendation about the use in the NHS of pembrolizumab for untreated PD-L1-positive, locally advanced or metastatic urothelial cancer when cisplatin is unsuitable.	17/02/21	Listed as RED drug in 8.1.5	Add link to NICE TA - Not approved for this indication.

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TA675: Vernakalant for the rapid conversion of recent onset atrial fibrillation to sinus rhythm	17/02/21	Not listed in Chapter 2.3.2	Not approved for this indication
(terminated appraisal)			
Commissioning: CCG			
NICE is unable to make a recommendation about the use in			
the NHS of vernakalant for the rapid conversion of recent onset atrial fibrillation (7 days or less) to sinus rhythm in			
adults who have not had surgery.			
TA677: Autologous anti-CD19-transduced CD3+	24/02/21	Not listed as not a drug	No action.
cells for treating relapsed or refractory mantle			
cell lymphoma Commissioning: NHSE			
Treatment with autologous anti-CD19-transduced CD3+			
cells is recommended for use within the Cancer Drugs Fund			
as an option for relapsed or refractory mantle cell lymphoma in adults who have previously had a Bruton's tyrosine			
kinase (BTK) inhibitor. It is only recommended if the			
conditions in the managed access agreement for			
autologous anti-CD19-transduced CD3+ cells treatment are followed			
TA676: Filgotinib for treating moderate to severe	24/02/21	Not listed in chapter 10.1.3	Add to formulary
rheumatoid arthritis			as RED drug with
Commissioning: CCG			link to NICE TA.
Filgotinib, with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose			Potential Cost
disease has responded inadequately to intensive therapy			implications been
with 2 or more conventional disease-modifying antirheumatic drugs (DMARDs), only if:			flagged to CCGs
disease is moderate or severe (a disease activity			as part of annual
score [DAS28] of 3.2 or more) and			horizon scanning.
 the company provides filgotinib according to the 			
commercial arrangement.			
Filgotinib, 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 filgotinib according to the 			
commercial arrangement.			
Filgotinib, 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 filgotinib according to the			
commercial arrangement. Filgotinib can be used as monotherapy when methotrexate			
is contraindicated or if people cannot tolerate it, when the			
criteria in sections 1.1, 1.2 or 1.3 are met.			
Choose the most appropriate treatment after discussing the advantages and disadvantages of the treatments available			
with the person having treatment. If more than 1 treatment			
is suitable, start treatment with the least expensive drug			
(taking into account administration costs, dose needed and product price per dose). This may vary from person to			
person because of differences in how the drugs are taken			
and treatment schedules. Continue treatment only if there is a moderate response			
measured using European League Against Rheumatism			
(EULAR) criteria at 6 months after starting therapy. If this			
initial response is not maintained at 6 months, stop treatment.			
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.			
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TA678: Omalizumab for treating chronic rhinosinusitis with nasal polyps (terminated	24/02/21	Listed as RED drug in 3.4.2	Add as Not approved for this
appraisal)			indication.
Commissioning: CCG, tariff excluded			
NICE is unable to make a recommendation about the use in			
the NHS of omalizumab for treating chronic rhinosinusitis			
with nasal polyps because Novartis Pharmaceuticals 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 will not be launched in			
the UK for treating this indication.			
	24/02/21	Not listed	For information
HST14: Metreleptin for treating lipodystrophy	24/02/21	Not listed	For information
Commissioning: NHSE			only.
Metreleptin is recommended, within its marketing			·
authorisation, as an option for treating the complications of			
leptin deficiency in lipodystrophy for people who are 2 years			
and over and have generalised lipodystrophy.			
Metreleptin is recommended as an option for treating the			
complications of leptin deficiency in lipodystrophy for people			
who are 12 years and over, have partial lipodystrophy, and			
do not have adequate metabolic control despite having			
standard treatments. It is only recommended if they have an HbA1c level above 7.5%, or fasting triglycerides above 5.0			
mmol/litre, or both.			
	24/02/21	Listed as GREEN drug in	Add to formulary
TA679: Dapagliflozin for treating chronic heart	24/02/21	Listed as GREEN drug in	Add to formulary
failure with reduced ejection fraction		6.1.2.3	as AMBER SI for
Commissioning: CCG			this indication with
Dapagliflozin is recommended as an option for treating			link to NICE TA.
symptomatic chronic heart failure with reduced ejection			
fraction in adults, only if it is used as an add-on to optimised			Noted South Tees
standard care with:			Cardiology are
 angiotensin-converting enzyme (ACE) inhibitors 			developing a local
or angiotensin-2 receptor blockers (ARBs), with			guideline to
beta blockers, and, if tolerated, mineralocorticoid			support
receptor antagonists (MRAs), or			implementation of
 sacubitril valsartan, with beta blockers, and, if 			this NICE TA.
tolerated, MRAs.			UIIS NICE TA.
Start treatment of symptomatic heart failure with reduced			
ejection fraction with dapagliflozin on the advice of a heart			
failure specialist. Monitoring should be done by the most			
appropriate healthcare professional.			
People whose symptoms continue or worsen on optimised			
doses of standard care based on ACE inhibitors or ARBs			
can only start sacubitril valsartan under the supervision of a			
specialist with access to a multidisciplinary team. So			
dapagliflozin should only be started on advice from a heart			
failure specialist in primary, secondary or community care.			
TA680: Lenalidomide maintenance treatment	03/03/21	Listed as RED drug in	Add link to NICE
after an autologous stem cell transplant for newly		8.2.4	TA.
diagnosed multiple myeloma			No cost impact to
Commissioning: NHSE			CCGs as NHSE
Lenalidomide is recommended as maintenance treatment			commissioned.
after an autologous stem cell transplant for newly diagnosed			commissioneu.
multiple myeloma in adults, only if the dosage schedule is			
10 mg per day on days 1 to 21 of a 28-day cycle and the			
company provides lenalidomide according to the			
commercial arrangement.			

TA681: Baricitinib for treating moderate to severe	03/03/21	Listed as RED drug in	Add to formulary
atopic dermatitis		10.1.3	as RED drug in
Commissioning: CCG, tariff excluded			chapter 13 with
Baricitinib is recommended as an option for treating moderate to severe atopic dermatitis in adults, only if the			link to NICE TA.
disease has not responded to at least 1 systemic			
immunosuppressant, such as ciclosporin, methotrexate,			
azathioprine and mycophenolate mofetil, or these are not			
suitable, and the company provides it according to the			
commercial arrangement.			
Assess response from 8 weeks and stop baricitinib if there			
has not been an adequate response at 16 weeks, defined			
as a reduction of at least 50% in the Eczema Area and			
Severity Index score (EASI 50) from when treatment started			
and 4 points in the Dermatology Life Quality Index (DLQI)			
from when treatment started.			
When using the EASI, take into account skin colour and			
how this could affect the EASI score, and make appropriate clinical adjustments.			
When using the DLQI, take into account any physical,			
psychological, sensory or learning disabilities, or			
communication difficulties that could affect the responses to			
the DLQI, and make any appropriate adjustments.			
TA682: Erenumab for preventing migraine	10/03/21	Not listed	Add to formulary
Commissioning: CCG, tariff excluded			as RED drug with
Erenumab is recommended as an option for			link to NICE TA.
preventing migraine in adults, only if they have 4 or			
more migraine days a month, at least 3 preventive			
drug treatments have failed, the 140 mg dose of			
erenumab is used and the company provides it			
according to the commercial arrangement.			
Stop erenumab after 12 weeks of treatment if in			
episodic migraine (less than 15 headache days a			
month) the frequency does not reduce by at least			
50% OR in chronic migraine (15 headache days a			
month or more with at least 8 of those having			
features of migraine) the frequency does not reduce			
by at least 30%.			
TA683: Pembrolizumab with pemetrexed and	10/03/21	Listed as RED drug in	Add link to NICE
platinum chemotherapy for untreated, metastatic,		8.1.5	TA.
non-squamous non-small-cell lung cancer			
Commissioning: NHSE			
Pembrolizumab with pemetrexed and platinum			
chemotherapy is recommended as an option for untreated,			
metastatic, non-squamous non-small-cell lung cancer			
(NSCLC) in adults whose tumours have no epidermal			
growth factor receptor (EGFR)-positive or anaplastic			
lymphoma kinase (ALK)-positive mutations. This is only if it is stopped at 2 years of uninterrupted treatment, or earlier if			
the disease progresses and the company provides		1	
pembrolizumab according to the commercial arrangement			
pembrolizumab according to the commercial arrangement.	17/03/21	Listed as RED drug in	Add link to NICE
TA684: Nivolumab for adjuvant treatment of	17/03/21	Listed as RED drug in	Add link to NICE
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node	17/03/21	Listed as RED drug in 8.1.5	Add link to NICE TA.
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease	17/03/21	•	
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease Commissioning: NHSE	17/03/21	•	
TA684: Nivolumab for adjuvant treatment ofcompletely resected melanoma with lymph nodeinvolvement or metastatic diseaseCommissioning: NHSENivolumab is recommended, within its marketing	17/03/21	•	
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic diseaseCommissioning: NHSENivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of	17/03/21	•	
TA684: Nivolumab for adjuvant treatment ofcompletely resected melanoma with lymph nodeinvolvement or metastatic diseaseCommissioning: NHSENivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node	17/03/21	•	
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic diseaseCommissioning: NHSENivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only	17/03/21	•	
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic diseaseCommissioning: NHSENivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the company provides nivolumab according to the	17/03/21	•	
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic diseaseCommissioning: NHSENivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the company provides nivolumab according to the commercial arrangement.		8.1.5	
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic diseaseCommissioning: NHSENivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the company provides nivolumab according to the commercial arrangement.TA685: Anakinra for treating Still's disease	17/03/21 31/03/21	•	TA.
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic diseaseCommissioning: NHSENivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of 		8.1.5 Listed as Red drug in	TA. Add link to NICE
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic diseaseCommissioning: NHSENivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the company provides nivolumab according to the 		8.1.5 Listed as Red drug in	TA. Add link to NICE
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic diseaseCommissioning: NHSENivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the company provides nivolumab according to the 		8.1.5 Listed as Red drug in	TA. Add link to NICE
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic diseaseCommissioning: NHSENivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the company provides nivolumab according to the 		8.1.5 Listed as Red drug in	TA. Add link to NICE
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic diseaseCommissioning: NHSENivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the company provides nivolumab according to the 		8.1.5 Listed as Red drug in	TA. Add link to NICE
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease Commissioning: NHSE Nivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the company provides nivolumab according to the commercial arrangement. TA685: Anakinra for treating Still's disease Commissioning: NHSE Anakinra is recommended as an option for treating Still's disease with moderate to high disease activity, or continued disease activity after non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. It is only recommended for adult-onset Still's disease that has responded inadequately to 2 or more conventional disease-modifying antirheumatic		8.1.5 Listed as Red drug in	TA. Add link to NICE
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TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease Commissioning: NHSE Nivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the company provides nivolumab according to the commercial arrangement. TA685: Anakinra for treating Still's disease Commissioning: NHSE Anakinra is recommended as an option for treating Still's disease with moderate to high disease activity, or continued disease activity after non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. It is only recommended for adult-onset Still's disease that has responded inadequately to 2 or more conventional disease-modifying antirheumatic drugs (DMARDs) OR systemic juvenile idiopathic arthritis in people 8 months and older with a body weight of 10 kg or		8.1.5 Listed as Red drug in	TA. Add link to NICE
TA684: Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease Commissioning: NHSE Nivolumab is recommended, within its marketing authorisation, as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the company provides nivolumab according to the commercial arrangement. TA685: Anakinra for treating Still's disease Commissioning: NHSE Anakinra is recommended as an option for treating Still's disease with moderate to high disease activity, or continued disease activity after non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids. It is only recommended for adult-onset Still's disease that has responded inadequately to 2 or more conventional disease-modifying antirheumatic drugs (DMARDs) OR systemic juvenile idiopathic arthritis in		8.1.5 Listed as Red drug in	TA. Add link to NICE

TA686: Blinatumomab for previously treated	31/03/21	Listed as Red drug in 8.1.5	Add link to NICE
Philadelphia-chromosome-positive acute			TA and that not
lymphoblastic leukaemia (terminated appraisal)			approved for this
Commissioning: NHSE			indication.
NICE is unable to make a recommendation about the use in			
the NHS of blinatumomab for treating Philadelphia-			
chromosome-positive relapsed or refractory acute lymphoblastic leukaemia. This is because Amgen UK has			
confirmed that it does not intend to make an evidence			
submission for the appraisal. Amgen UK considers that			
there is unlikely to be enough evidence that the technology			
is a cost-effective use of NHS resources for this population.			
TA687: Ribociclib with fulvestrant for treating	31/03/21	Listed as Red drug in 8.1.5	Add link to NICE
hormone receptor-positive, HER2-negative	01/00/21		TA.
advanced breast cancer after endocrine therapy			
Commissioning: NHSE			
Ribociclib plus fulvestrant is recommended as an option for			
treating hormone receptor-positive, human epidermal			
growth factor receptor 2 (HER2)-negative, locally advanced			
or metastatic breast cancer in adults who have had previous			
endocrine therapy only if exemestane plus everolimus is the			
most appropriate alternative to a cyclin-dependent kinase 4			
and 6 (CDK 4/6) inhibitor, and the company provides			
ribociclib according to the commercial arrangement.			
TA688: Selective internal radiation therapies for	31/03/21	Non-applicable – is a	None as these
treating hepatocellular carcinoma		medical device not a drug	types of products
Commissioning: NHSE			are not normally
The selective internal radiation therapy (SIRT) SIR-Spheres			listed on the
is recommended as an option for treating unresectable			formulary.
advanced hepatocellular carcinoma (HCC) in adults, only if			
used for people with Child–Pugh grade A liver impairment			
when conventional transarterial therapies are inappropriate, and the company provides SIR-Spheres according to the			
commercial arrangement.			
The SIRT TheraSphere is recommended as an option for			
treating unresectable advanced HCC in adults, only if used			
for people with Child–Pugh grade A liver impairment when			
conventional transarterial therapies are inappropriate, and			
the company provides TheraSphere according to the			
commercial arrangement.			
The SIRT QuiremSpheres is not recommended for treating			
unresectable advanced HCC in adults.			
NG190: Secondary bacterial infection of eczema	02/03/21	Fusidic acid 2% topical:	Add link to start of
and other common skin conditions: antimicrobial		Flucloxacillin	Chapter 5.
prescribing		Clarithromycin	
Commissioning: CCG, tariff included		Erythromycin	
This guideline sets out an antimicrobial prescribing			
strategy for secondary bacterial infection of eczema			
and covers infection of other common skin			
conditions. It aims to optimise antibiotic use and			
reduce antibiotic resistance. The recommendations			
are for adults, young people and children aged 72			
hours and over. They do not cover diagnosis.			
NG191: COVID-19 rapid guideline: managing	23/03/21	All relevant drugs on	Add link to start of
COVID-19		formulary.	Chapter 5
This guideline covers the management of COVID-19 for			
children, young people and adults in all care settings. It			
brings together our existing recommendations on managing			
COVID-19 so that healthcare staff and those planning and			
delivering services can find and use them more easily. The			
guideline includes new recommendations on therapeutics,			
and we will update the guideline further as new evidence			
emerges. The guideline underes and replaces our COVID 19 repid			
The guideline updates and replaces our COVID-19 rapid guidelines on critical care in adults, managing symptoms			
(including at the end of life) in the community, managing			
suspected or confirmed pneumonia in adults in the			
community, acute myocardial injury, antibiotics for			
pneumonia in adults in hospital, acute kidney injury in			
hospital, and reducing the risk of venous thromboembolism			
in over 16s with COVID-19.			

NG192: Caesarean birth This guideline covers when to offer caesarean birth, discussion of caesarean birth, procedural aspects of the operation, and care after caesarean birth. It aims to improve	31/03/21	All relevant drugs on formulary.	For information only.
the consistency and quality of care for women who are thinking about having a caesarean birth or have had a previous caesarean birth and are pregnant again.			
NG80: Asthma: diagnosis, monitoring and	22/03/21		For information
chronic asthma management In March 2021, NICE highlighted the importance of including advice in the personalised action plan on minimising indoor air pollution and reducing exposure to outdoor air pollution.	(updated)		only.
NG144: Cannabis-based medicinal products Commissioning: CCG, tariff included March 2021: NICE has issued a clarification on recommendations for the use of unlicensed cannabis-based medicinal products for severe treatment-resistant epilepsy. This clarification has the same status as the guideline and should be read alongside it. This clarification relates to the interpretation of the aspect of the guideline concerned with the use of cannabis-based medicinal products to treat severe treatment-resistant epilepsy in children. (NICE has published separate technology appraisal guidance on cannabidiol with clobazam for treating seizures associated with Lennox- Gastaut syndrome and Dravet syndrome). The guideline made research recommendations for the use of unlicensed cannabis-based medicinal products for severe treatment-resistant epilepsy. The committee took the view, based on the evidence available at the time, that there was insufficient evidence of safety and effectiveness to support a population-wide practice recommendation (that is, a recommendation relating to the whole population of people with severe treatment-resistant epilepsy). The fact that NICE made no such population-wide recommendation should not however be interpreted by healthcare professionals as meaning that they are prevented from considering the use of unlicensed cannabis- based medicinal products where that is clinically appropriate in an individual case. Patients in this population can be prescribed cannabis-based medicinal products if the healthcare professional considers that that would be appropriate on a balance of benefit and risk, and in consultation with the patient, and their families and carers or guardian. There is no recommendation against the use of cannabis- based medicinal products. For more information about why the committee decided not to recommend against use of these products, see the rationale section of the guideline.	22/03/21 (updated)	Only cannabidiol (Epidyolex) listed on the formulary as per the NICE TAs in chapter 4.8.1	No further action. Unlicensed cannabis-based medicinal products for severe treatment- resistant epilepsy are non-formulary and therefore available where that is clinically appropriate in an individual case. They are not listed as NOT APPROVED. No changes to APC guidance adopted from NE Prescribing Forum and approved 17.1.2019 required. This states all such prescribing should be done by hospital specialist, not primary care.
Drug Safety Advice	Date issued	Current formulary	Recommended action for APC
Ulipristal acetate 5mg (Esmya): further restrictions due to risk of serious liver injury The indication of ulipristal acetate 5mg for uterine fibroids has been further restricted due to the risk of serious liver injury and liver failure, with some cases requiring liver transplantation. Although the temporary suspension has been lifted, this medicine should only be used for intermittent treatment of moderate to severe symptoms of uterine fibroids before menopause and when surgical procedures (including uterine fibroid embolisation) are not suitable or have failed.	18/02/21	NOT APPROVED in chapter 6.4.1.2 due to MHRA Drug Safety Update (Mar 2020): Esmya (ulipristal acetate): suspension of the licence due to risk of serious liver injury	Add link to MHRA DSU. CDDFT to seek a new formulary application to add back into the formulary if specialists wish to use again.
Pregabalin (Lyrica): reports of severe respiratory depression Pregabalin has been associated with infrequent reports of severe respiratory depression, including some cases without the presence of concomitant opioid medicines. Patients with compromised respiratory function, respiratory or neurological disease, renal impairment; those using concomitant central nervous system (CNS) depressants; and people older than 65 years might be at higher risk of experiencing these events and adjustments in dose or dosing regimen may be necessary.	18/02/21	Green drug in chapter 4.7.3 (neuropathic pain) and Amber SI for epilepsy/anxiety.	Add link to MHRA DSU.

Alkindi (hydrocortisone granules): risk of acute adrenal insufficiency in children when switching from hydrocortisone tablet formulations to granules When children receiving replacement therapy for adrenal insufficiency are being switched from hydrocortisone tablets to Alkindi granules, parents or carers should be informed of the need to be extra vigilant for symptoms of adrenal insufficiency. Medicines in pregnancy and breastfeeding: new	18/02/21	AMBER SI in chapter 6.2.3 To replace the use of crushing 5 and 10mg tablets when smaller doses are required. Approved for primary and secondary adrenal insufficiency in paediatric patients. n/a	Add link to MHRA DSU.
initiative for consistent guidance; report on optimising data for medicines used during pregnancy Information on the newly launched Safer Medicines in Pregnancy and Breastfeeding Consortium and a new report on optimising data on medicines used during pregnancy.			only.
COVID-19 vaccines and medicines: updates for February 2021 A summary of advice recently issued by the MHRA relating to coronavirus (COVID-19), up to 16 February 2021.	18/02/21	Green drug in chapter 14	For information only.
 Letters and drug alerts sent to healthcare professionals in January 2021 Voriconazole 200 mg powder for solution for infusion: Interim supply arrangements to mitigate supply disruption Esmya (ulipristal acetate) 5mg: Indications for uterine fibroids restricted due to concerns of severe liver injury Accord Thalidomide 50mg hard capsules: Pregnancy Prevention Programme to minimise the risk of teratogenicity. To facilitate the implementation of the PPP during the coronavirus (COVID-19) pandemic, we have published temporary guidance. Company led medicines recall: Instanyl 100mcg nasal spray solution (EU/1/09/531/015). Issued 18 January 2021. Company led medicines recall: Respreeza 1,000 mg powder and solvent for solution for infusion (EU/1/15/1006/001). Issued 20 January 2021. 	18/02/21	For info.	For info.
Bendamustine (Levact): increased risk of non- melanoma skin cancer and progressive multifocal encephalopathy (PML) Periodically perform skin examinations in patients on bendamustine-containing regimens and consider PML in the differential diagnosis for patients on bendamustine with new or worsening neurological, cognitive, or behavioural signs or symptoms.	23/03/21	RED drug in chapter 8.1.1	Add link to MHRA DSU.
COVID-19 vaccines and medicines: updates for <u>March 2021</u> A summary of advice recently issued by the MHRA relating to coronavirus (COVID-19), up to 18 March 2021.	23/03/21	Green drug in chapter 14	For information only. No further action required.
Letters and drug alerts sent to healthcare professionals in February 2021	23/03/21	For info.	For info.
Requested formulary amendments	BNF Chapter	Reasoning	Recommended action for APC
Calmurid - remove from formulary as discontinued Commissioning: CCG, in tariff	13.2.1	Remove from formulary as discontinued	Delete from formulary
Adalimumab Commissioning: NHSE, tariff excluded	10.1.3	NOT APPROVED for this indication as per the NHSE policy - Clinical Commissioning Policy Statement Use of adalimumab for refractory chronic non-bacterial osteomyelitis osteitis (CNO) (all ages)	Add as not approved for this indication

Monthly oral ibandronic acid 150mg film coated tablets - change from DNP to Green Commissioning: CCG, in tariff	6.6.2.2	To review the current formulary position for monthly oral ibandronic acid as currently listed as non-formulary but should be on the formulary as per NICE TA464 alongside all the other oral bisphosphates for osteoporosis. It appears entry on CD&TV DNP list comes from previous CD&D DNP list going back as far as May 20211 i.e. pre-dates NICE TA and as not been updated to reflect NICE TA.	Change from NOT APPROVED to Green drug
Prucalopride for chronic constipation in men - add as AMBER SI Commissioning: CCG, in tariff	1.6.7	Prucalopride (Resolor®) is indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief i.e. in men as well as women since the product license was updated in May 2015. Currently it is only on the formulary as AMBER SI for use in women as per NICE TA211.	Add as AMBER SI for use men as well as women in whom at least two laxatives from different classes, at the highest tolerated recommended doses for at least 6 months has failed to provide adequate relief and invasive treatment for constipation is being considered.
Spironolactone RAG review Commissioning: CCG, in tariff	2.2.3	The FSG has been asked to review the RAG status of Spironolactone on the formulary (primarily for its hypertension indication) following a query at March 2021 APC when drug monitoring guidelines approved. It was agreed to class as AMBER SI for heart failure and GREEN for hypertension. This is in line with other local formularies and relevant NICE Clinical Guidelines.	Class as AMBER SI for heart failure or ascites and GREEN for hypertension. This is in line with other local formularies and relevant NICE Clinical Guidelines.
Clonidine 25mcg tablets for sedation Commissioning: CCG, in tariff	2.5.2	Following a request from CDDFT the FSG agreed to recommend to APC adding to the formulary as a RED drug for use in intensive care only.	Add to formulary as RED drug.
Cyproheptadine 4mg tablets for Serotonin syndrome Commissioning: CCG, in tariff	17	Following a request from CDDFT the FSG agreed to recommend to APC adding to the formulary as a RED drug for use in emergency management of serotonin syndrome in hospital only. Note on the list of Royal College of Medicine recommended antidotes to be available within a hospital within one hour.	Add to formulary as RED drug.

Cimetidine, Famotidine and Nizatidine (oral forms) Commissioning: CCG, in tariff	13.1	Add formulary as Green drugs due to ongoing long- term supply issues with ranitidine.	Add to formulary as GREEN drug.
Droperidol 2.5mg/ml injection Commissioning: CCG, in tariff	4.6e	Agreed to add formulary as a Red drug for post surgery nausea & vomiting following a request from CDDFT	Add to formulary as RED drug.
Sodium Glycerophosphate 21.6% injection Commissioning: CCG, in tariff	9.5.2.1	Agreed to add formulary as a Red drug as an alternative to phosphate polyfusor following a request from CDDFT.	Add to formulary as RED drug.

ACTION:

• RDTC to update the online formulary with the approved changes.

12. New Drug Applications

Buprenorphine oral lyophilisate (Espranor® - resubmission

A new formulary submission for Espranor® (Buprenorphine SL) Formulary Application received from We Are With You - commissioned to provide specialist community drug and alcohol services in Redcar and Cleveland and Darlington – was presented to the APC.

A formulary application for Espranor® submitted by Spectrum Community Health CIC was previously discussed at the meeting of the County Durham & Tees Valley Formulary Subgroup on the 13th February 2020 and the decision not to approve ratified by the full County Durham & Tees Valley Area Prescribing Committee on the 12th March 2020. Spectrum Community Health CIC have never appealed this decision and continue to comply with it.

It was noted that this latest application still does have the support of the local authorities who are the commissioners of drug misuse services nor does is there desire for Espranor® to be added to the formulary from other local providers of drug misuse services.

The APC agreed not to approve the formulary application as:

- No support from APC stakeholder local authorities as commissioners of substance misuse services to add Espranor® (Buprenorphine SL) to CD&TV formulary.
- Since the last decision, as far as aware nothing has changed clinically or in guidance, and Espranor® is still significantly more expensive than generic buprenorphine s/l tablets. (APC does not consider Rebate schemes in its formulary decision making process).
- Concerns were expressed around patient safety implications including potential variation in bioavailability, confusion arising from multiple dosage forms of buprenorphine and the impact on community pharmacy supervised services. These risks have not changed.
- Risk of dispensing errors in community pharmacies from having Espranor® and other brands of sublingual buprenorphine both available when 2mg and 8mg strengths both available people may not realise the products and dose are different.
- No evidence provided in new application that supports statement form applicant that precludes patients from having a treatment choice which could give them a better experience and outcomes compared to currently used forms of sublingual buprenorphine.
- It has proved to be of great benefit i.e. diversion, clients who find being in community pharmacies a difficult experience and the speed of supervision benefits them again not real evidence provided to support this statement.

ACTION:

• RDTC to respond to applicant with reasons for not approving formulary application.

13. NTAG Update

The APC noted the following new recommendations following the February 2021 NTAG meeting and agreed that the formulary would reflect the NTAG recommendation:

 Flash Glucose Monitoring – updated to include learning disability in use in pregnancy in Type 2 diabetes. The APC noted the following reviewed recommendations following the February 2021 NTAG meeting:

- Teriparatide for atypical fractures reviewed & no changes
- Xoneva® for nausea & vomiting in pregnancy reviewed & no changes

The APC also received the February 2021 NTAG Workplan for information.

14. RMOC Update

RMOC Shared-Care for Medicines Guidance – A Standard Approach

The APC discussed the RMOC Shared Care for Medicines Guidance: A Standard Approach which has just been published.

The APC was supportive of this document and what is trying to achieve in terms of standardisation across England.

The RMOC guidance includes a list of 18 drugs which it deems to be shared care and a national shared care template will now be drafted for each of these shared care drugs (though no timescales as to when this will be completed). In addition to the list of 18 nationally agreed shared care drugs local APCs can add/approve other drugs with they deem to shared care locally e.g. melatonin, antipsychotic LAIs, valproate.

Guidance also includes a suggested national template for Shared Care Guidelines plus letter templates for requesting/accepting/refusing shared care. It needs to be recognised locally that local adoption/implementation of these letter templates may take time to imbed, and require engagement with Trusts/individual specialities. In some Trusts these letter templates are already used with varying degrees of success, in others this will be a new a concept. There will also need to be work done to explore how these templates can be built into current electronic clinical record systems used by GP practices and Trusts.

The APC agreed to adopt this national guidance on shared care as local policy, together with the national template for SCGs and letter templates for requesting/accepting/refusing shared care as they come up for review, or a national SCG becomes available.

It was agreed that the APC should work with stakeholders to support local adoption of this national guidance as it is now the nationally agreed best practice around shared care and transfer of shared care.

It was also agreed that local shared care guidelines would generally be updated as they come up naturally for review to mirror any available RMOC template unless there was significant differences that required a more urgent review of the local version. The first priority locally will be updating DMARD shared care guidelines.

RMOC Shared Care Workplan

Circulated for information. APC members will be notified when a draft RMOC SCG is released for consultation so they can participate in the consultation process.

Updated CD&T APC Shared Care Template

An updated CD&T APC Shared Care Template based on the RMOC template was agreed for all new local shared care guidelines and guidelines as they come up for review was approved by the APC.

ACTION:

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

Implications of RMOC guidance on Local Shared Care Workstream

In order to prevent regional duplication of national work, it was proposed that the ICS wide approach to shared care agreed in November 2020 is modified, with the APCs agreeing instead to participate in the RMOC national shared care guideline consultations when these are published. We would then work collaboratively on the adoption of the final RMOC Shared Care Guidance for Immune Modifying Drugs when the final versions are published. This approach was supported by the CD&T APC and it was agreed to put this to the two other regional APCs. It was noted APC may need to extend expiry dates of some existing shared care guidelines until

national guidelines are published, and this was agreed.

ACTION:

• RDTC to share this update paper and proposal with other APCs in region.

15. CDDFT CSTC Update

Nothing to report from last meeting except have approved guideline for us of SC Furosemide by Community Heart Failure Nurses which will come to next APC for information.

16. NTHFT D&T Update

No update available. Minutes shared for information.

17. STHFT D&T Update

Verbal update on May 2021 meeting given. All approved drugs will come to the next APC for the formulary to be updated. The discussions around hydroxychloroquine eye monitoring at STHFT and lack of capacity were also noted

18. Primary Care Prescribing Committee Updates

County Durham CCG – written update to be shared post-meeting. Tees Valley CCG – verbal update given.

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

19. Guidance for Hypogonadism Management in Primary Care

The final draft of new APC Guidance for Hypogonadism Management in Primary Care was presented to the APC and approved.

ACTION:

- RDTC to arrange for approved version to be added to APC pages of NECS website.
- 20. CAS Alert Covid-19 Therapeutic Alert Inhaled Budesonide For Adults (50 Years And Over) With Covid-19

The APC received this alert for information and noted that apart from adding a link to the CAS alert in the formulary there was no further action for the APC at this stage.

ACTION:

• RDTC to update the online formulary with link to CAS alert.

Part 5 – Other Items of Business

21. New North Yorkshire & York APC

A verbal update was received for information on the creation of the new North Yorkshire & York APC. This may have implications for STHFT and patients they see from parts of North Yorkshire. The new North Yorkshire & York APC is to start meeting from July 2021. The plan is to work closely with the CD&TV APC and align formularies where possible.

22. Steroid Emergency Cards - pathway and implementation plan

The APC noted that the actions and implementation plan being undertaken in primary care by CCG Medicines Optimisation Teams to ensure compliance with the NPSA Alert by the required deadline.

23. Changes to labelling of discharge medication at CDDFT

APC noted that all P and GSL medicines when used as per their product license supplied from a CDDFT Urgent Care Centre will now be supplied without a "supplied by CDDFT" sticker but that for Care Home patients a label with the patients name will still be applied at the point of supply

by the Urgent Care Centre.

24. Boron additives in Chloramphenicol drops

It was reported to the APC that some chloramphenicol eye drops have recently updated their SPCs to include a contra-indication in children under the age of 2, and this has raised a number of queries from prescribers.

The RCOphth have issued a useful Position Statement which states:

"Although more data on the concentration of borates in individual formulations of chloramphenicol are required, currently available data suggest that the recommended maximum daily dose of boron is unlikely to be exceeded with conventional eyedrop regimes, even for children under the age of two. At the present time, the College believes that the benefits of chloramphenicol eyedrops in paediatric ophthalmic practice for appropriate indications and with courses of appropriate duration outweigh the possible risks posed by boron ingestion. The RCOphth is seeking to work with the MHRA and the DHSC Senior Pharmacist Medicine Supply Team on this issue to ensure the advice given by all national bodies and suppliers is proportionate and supports clinical requirements."

The APC noted recent changes to product SPCs contra-indication use in under 2 year olds, and that further guidance expected shortly from MHRA.

ACTION:

• CCG MO Teams to raise awareness of the issue with primary care prescribers.

25. CD&D DVT Pathway and Out of Hours Provision

The APC discussed a recent incident regarding the CD&D DVT Pathway and Out of Hours provision of Rivaroxaban and if any changes to the pathway are required as result. APC asked to confirm they arrangement for out of hours supply of Rivaroxaban for a DVT, as recently a patient needed to attend A&E for a supply and this may not have been necessary. It was agreed that no changes are required as CDDFT Out of Hours Team should be able to supply Rivaroxaban to a patient who may require it out of hours rather than sending the patient to A&E.

ACTION:

• JH to check and confirm that CDDFT OOH services have access to rivaroxaban.

26. Postcode/Interface Issues with other Formularies in Region

There remain ongoing issues around differences in RAG between the three local APCs in the NE&NC, particularly around drugs initiated by Tertiary Centres.

The latest issue to arise is nebulised gentamicin for non-CF indications which is Green+ in NoT but RED in Sunderland and CD&TV formularies (though Sunderland looking to review their formulary position). To note a similar drug nebulised Colomycin for non-CF indication is already Green+/Amber SI on CD&TV formulary.

The APC discussed and a proposal that where a post code issue has been identified for what is considered a tertiary centre initiated drug that the mechanism simply be that the other APCs are formally asked to consider adopting the position of the "originator APC" rather than going through a full application process on the basis that a robust governance process can be assumed. This would involve discussing with local specialists / MO representatives and if significant concerns / differences arose then these would need to be discussed with the originator APC. To note though CD&TV have largely already done this as CD&D formulary was originally based on NoT formulary, but that further work will be done to agree a consistent formulary RAG status for tertiary centre drugs across the region.

After discussion the APC agreed the following:

- Approve change to formulary for Nebulised Gentamicin from RED to AMBER SI as per NoT position: For long term therapy in non-cystic fibrosis bronchiectasis usually in patients having > 3 exacerbations per annum with an organism identified as being sensitive to gentamicin. (note: NoT have a GP information leaflet in place to support this).
- CD&T APC adopt the proposal that where a post code issue for a tertiary centre drug has been identified the mechanism simply be that the other APCs are formally asked to consider adopting the position of the "originator APC" rather than going through a full

application process on the basis that a robust governance process can be assumed.

ACTION:

- RDTC to update the online formulary with the approved change for nebulised gentamicin.
- RDTC to work with NuTH Formulary Pharmacist to agree RAG position for an agreed list on tertiary centre drugs, and include the other APCs/Trusts as necessary.

27. Changes to Management of Type 2 Diabetes – Implications for Prescribing Budgets

The latest paper prepared by regional Prescribing Forum to go the regional Chief Finance Officers Group outlining the financial pressures was circulated to the APC for awareness as the local CAG and Diabetes Board are keen to pursue new guidance.

In Summary – the financial risks are no different. NICE is only finalising CKD guidance and two Technology Appraisals this summer but not addressing the whole of the diabetes guidance still and no one but NICE has the capacity to do long term economic benefits of these medicines. There is a very keen appetite in the professional networks across the region to now move with the European guidance which our guidelines were totally based on. Cardiology are also keen to use and are using in nearly any patient that is diabetic a SGLT2 so the cost impact continues to grow. It was noted that CCG Finance Teams have flagged this to CCG Executive Committees as an area of high financial risk. It was also noted that the clinical network are in the process of forming a working group to try and progress. The APC recognised the need for these guidelines to be updated to reflect latest clinical evidence but this needs to be supported by robust financial modelling. Concerns around the financial risk/implications will continue to be raised on the APC's behalf regionally and nationally.

28. Oxycodone Formulary Choice

Following discussions at NENC Prescribing Forum the APC discussed and agreed not to progress a switch from Longtec® to Oxypro® at this time in County Durham & Tees Valley because may dilute message /work being undertaken around reducing use of opioids overall, concerns around short term savings only, and also cost implications for secondary care.

Part 6 – Standing Items (for information only)

- **29.** Formulary Steering Group Minutes February 2021 For information.
- **30. TEWV D&T Minutes January 2021** For information.
- **31. CDDFT Clinical Standards and Therapeutics Committee Minutes April 2021** For information.
- **32.** North Tees & Hartlepool Hospitals D&T Minutes April 2021 For information.
- **33.** South Tees Hospitals D&T Minutes Not met since January 2021.
- **34. RDTC Horizon Scanning March & April 2021** For information.
- **35.** NTAG Minutes December 2020 For information.

- **36.** NE&C CCG Prescribing Forum Minutes March 2021 For information.
- **37.** NEAS Medicines Group Minutes since November 2019 Not yet available.
- **38.** South Tyneside & Sunderland APC Minutes & Decision Summary Not yet available.

Chairman's Action

• APC Drug Monitoring Recommendations - final version approved via Chair's Action.

Any Other Business

NICE Updated Atrial Fibrillation Guidelines

The APC noted that NICE published its updated Atrial Fibrillation Guidelines in April 2021. This continues the move to using DOACs over warfarin. It will be included in FSG update to the next APC meeting for further discussion on local adoption. In the meantime the outdated guidance/patient decision aid in County Durham & Darlington has been removed from the APC pages of the NECS website.

Date and time of next meeting:

Thursday 8th July 2021, 9am – 11.30am, virtual meeting via Microsoft Teams tele/videoconference – details to be circulated