NHS

County Durham & Tees Valley
Area Prescribing Committee

County Durham and Tees Valley Area Prescribing Committee

Thursday 12th November 2020
9am – 11.30am
Held Via Microsoft Teams

Present

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

In attendance
Adam & Paige – Pre-registration Pharmacists at CDDFT - observing

The meeting was quorate and remained quorate throughout.

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

Part 1

1. Apologies for Absence:
Claire Jones

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:
Shafie Kamaruddin – oral semaglutide – interest as diabetes consultant but no direct financial interest.

3. Minutes and Decision Summary of the Previous APC Meeting Held on 10th September 2020
The minutes were accepted as a true and accurate record.
The decision summary of the September 2020 meeting was accepted as a true and accurate record.

4. Matters Arising Not On the Agenda
Nil.

5. Action Log
Priadel® Discontinuation from April 2021
Update on today's agenda. ITEM NOW CLOSED.

TA631: Fremanezumab for preventing migraine
Was sent to CCG Executive Committees as above financial threshold of level of delegated authority of APC and approved. ITEM NOW CLOSED.

Melatonin (Slenyto®) Formulary Application
On today's agenda.

Primary Care Guidance for Prescribing and Monitoring Post Bariatric Surgery
Following approval at September 2020 APC now approved via Chair's Action and now added to website. ITEM NOW CLOSED.

CD&T APC Do Not Prescribe/Grey List
Now added to website. ITEM NOW CLOSED.

CD&D DVT Pathway – updated
Now added to website. ITEM NOW CLOSED
Still to confirm arrangements Out of Hours and if this pathway will adopted by Out of Hours teams.

CD&T APC Position Statement on Omega-3 Prescribing
Now added to website. ITEM NOW CLOSED.

CD&T APC Transanal Irrigation Guidelines
On today's agenda for final approval.

Pain Guidelines – updated
Now added to website. ITEM NOW CLOSED.

Hydroxychloroquine SCG
A working group has been set up in County Durham for hydroxychloroquine and it has met with all three consultants (dermatology, ophthalmology, dermatology) as well as commissioning team and MO team. There are issues and there is no pathway. This is all being captured in a paper regarding patients not being monitored.
Also Awaiting final RMOC South Guidance which was out for consultation in Oct 2020.
ID/JW have raised awareness of the issues around capacity/implementation within their respective CCGs.

CD&T Respiratory Guidelines – minor updates
Now added to website. 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
NTAG have issued a joint statement with GMMMG lobbying for NICE to look at financial modelling for these updated pathways nationally as soon as possible. Expecting update on NICE timetable for this work at the end of November 2020.
NE Prescribing Forum/CCG MO Leads are also preparing an options paper for CCG Executive Committees.

TA607: Rivaroxaban for CAD/PAD
After discussion in the cardiac network pre-COVID it was decided that this was not a priority for secondary or tertiary care cardiology. It was felt that cardiologists would make recommendations on a per patient basis as the opportunity arose but they did not anticipate large numbers of their patients under active follow-up being candidates for it. The cardiac network are not Are you in developing local guideline to support implementation of this NICE TA. Cardiologists also expect most patients to be initiated in primary care as they are patients on disease registers rather than under active review by a cardiologist, and are not asking GPs to refer any patient to a cardiologist to initiate treatment.
The question still remains then what GPs should do with historic patients on their lists who may be eligible, and also what tools are available to assess bleeding risk.

ACTION:

- **RDTC to see how other APCs are implementing this NICE TA and what guidance/supporting they have (if any) for GPs.**

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.

Aspirin in Pregnancy
Came about as supermarket shelves were empty of 75mg aspirin during the initial COVID-19 crisis After speaking to the midwifery service – normal supply routes are OK, and ladies are being directed to supermarkets to purchase when needed. After doing an internet trawl, the default seems to be to purchase from a supermarket/OTC, and a script from a GP if not possible After having contacted the midwife there are no more issues to report. ITEM NOW CLOSED.

Part 2 – Mental Health

6. TEWV Drug & Therapeutics Committee Feedback – September 2020
CW presented to the APC a briefing report highlighting the main issues discussed at the recent TEWV D&T.

7. Priadel® Discontinuation
The APC noted that the planned discontinuation of the Priadel® brand of lithium from April 2021 will not now go ahead. Essential Pharma have now withdrawn their earlier notice to remove Priadel® from the UK Market and will continue to make Priadel® available for the UK whilst they re-start negotiations on price with DHSC.

8. GP Information Sheet on Clozapine (updated)
The reviewed and updated GP Information Sheet on Clozapine to reflect August 2020 MHRA Drug Safety Alert around reminder monitoring was presented to and approved by the APC.

Part 4 – Formulary Issues

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

10. NICE TAs and MHRA Drug Safety Update – August & September 2020
These were presented to the group and the following actions were taken by the APC:

NICE Technology Appraisal/Guidance Title and date published	Date issued	Current formulary status	Recommended action for APC
TA640: Treosulfan with fludarabine for malignant disease before allogeneic stem cell transplant **Commissioning: NHSE** Treosulfan with fludarabine is recommended as an option for conditioning treatment before allogeneic haematopoietic stem cell transplant (allo-HSCT) for people with malignant diseases for whom a reduced intensity regimen, such as low-dose busulfan with fludarabine, would be suitable.	5/8/20	RED drug in chapter 8.1.1	Add link to NICE TA.

TA641: Brentuximab vedotin in combination for untreated systemic anaplastic large cell lymphoma **Commissioning: NHSE** Brentuximab vedotin with cyclophosphamide, doxorubicin and prednisone (CHP) is recommended, within its marketing authorisation, as an option for untreated systemic anaplastic large cell lymphoma in adults.	12/8/20	RED drug in chapter 8.1.5	Add link to NICE TA.
TA642: Gilteritinib for treating relapsed or refractory acute myeloid leukaemia **Commissioning: NHSE** Gilteritinib monotherapy is recommended as an option for treating relapsed or refractory FLT3-mutation-positive acute myeloid leukaemia (AML) in adults. Gilteritinib should not be given as maintenance therapy after a haematopoietic stem cell transplant.	12/8/20	Not listed in 8.1.5	Add to formulary as RED drug and add link to NICE TA.
TA643: Entrectinib for treating ROS1-positive advanced non-small-cell lung cancer **Commissioning: NHSE** Entrectinib is recommended, within its marketing authorisation, as an option for treating ROS1-positive advanced non-small-cell lung cancer (NSCLC) in adults who have not had ROS1 inhibitors.	12/8/20	Not listed in 8.1.5	Add to formulary as RED drug and add link to NICE TA.
TA644: Entrectinib for treating NTRK fusion-positive solid tumours **Commissioning: NHSE** Entrectinib is recommended for use within the Cancer Drugs Fund as an option for treating neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumours in adults and children 12 years and older if the disease is locally advanced or metastatic or surgery could cause severe health problems, they have not had an NTRK inhibitor before, and they have no satisfactory treatment options.	12/8/20	Not listed in 8.1.5	Add to formulary as RED drug and add link to NICE TA.
TA645: Avelumab with axitinib for untreated advanced renal cell carcinoma **Commissioning: NHSE** Avelumab with axitinib is recommended for use within the Cancer Drugs Fund as an option for untreated advanced renal cell carcinoma in adults.	02/09/20	Not listed in 8.1.5	Add to formulary as RED drug and add link to NICE TA.
TA646: Glasdegib with chemotherapy for untreated acute myeloid leukaemia (terminated appraisal) **Commissioning: NHSE** NICE is unable to make a recommendation on glasdegib with chemotherapy for untreated acute myeloid leukaemia because Pfizer did not provide an evidence submission.	02/09/20	Not listed in 8.1.5	No action.
TA647: Eculizumab for treating relapsing neuromyelitis optica (terminated appraisal) **Commissioning: NHSE?** NICE is unable to make a recommendation on eculizumab (Soliris) for treating relapsing neuromyelitis optica because Alexion Pharma UK did not provide an evidence submission.	02/09/20	RED drug in chapter 9.1.3	Add link to NICE TA that not recommended for this indication

TA648: Dupilumab for treating chronic rhinosinusitis with nasal polyps (terminated appraisal) **Commissioning: CCG, Tariff excluded** NICE is unable to make a recommendation on dupilumab (Dupixent) for treating chronic rhinosinusitis with nasal polyps because Sanofi 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.	09/09/20	RED drug in chapter 13.5.3	Add as NOT APPROVED drug in chapter 3.4.2 and add link to NICE TA	
TA649: Polatuzumab vedotin with rituximab and bendamustine for treating relapsed or refractory diffuse large B-cell lymphoma **Commissioning: NHSE** Polatuzumab vedotin with rituximab and bendamustine is recommended, within its marketing authorisation, as an option for treating relapsed or refractory diffuse large B-cell lymphoma in adults who cannot have a haematopoietic stem cell transplant.	23/09/20	Not listed in 8.1.5	Add to formulary as RED drug and add link to NICE TA.	
TA650: Pembrolizumab with axitinib for untreated advanced renal cell carcinoma **Commissioning: NHSE** Pembrolizumab with axitinib is not recommended, within its marketing authorisation, for untreated advanced renal cell carcinoma in adults.	30/09/20	RED drug in chapter 8.1.5	Add link to NICE TA that not recommended for this indication	
TA651: Naldemedine for treating opioid-induced constipation **Commissioning: CCG, in tariff** Naldemedine is recommended, within its marketing authorisation, as an option for treating opioid-induced constipation in adults who have had laxative treatment.	30/09/20	Not listed in chapter 1.6.6 (Naloxegol = AMBER SI)	Add to formulary as AMBER SI drug and add link to NICE TA. Formulary position to be as per the NICE TA as an option for treating opioid induced constipation in adults whose constipation has not adequately responded to laxatives.	
Drug Safety Advice	**Date issued**	**Current formulary status**	**Recommended action for APC**	
Stimulant laxatives (bisacodyl, senna and sennosides, sodium picosulfate) available over-the-counter: new measures to support safe use We have introduced pack size restrictions, revised recommended ages for use, and new safety warnings for over-the-counter stimulant laxatives (orally and rectally administered) following a national safety review.	18/8/20	For info	No action	Nil
Clozapine and other antipsychotics: monitoring blood concentrations for toxicity Monitoring blood concentrations of clozapine (Clozaril, Denzapine, Zaponex) for toxicity is now advised in certain clinical situations.	26/8/20	RED drug in 4.2.1	Add link to MHRA DSU.	
Denosumab 60mg (Prolia): increased risk of multiple vertebral fractures after stopping or delaying ongoing treatment Evaluate a patient's individual factors for benefits and risks before initiating treatment with denosumab 60mg, particularly in those with previous vertebral fracture	26/8/20	AMBER SC in 6.6.2	Add link to MHRA DSU.	

Baricitinib (Olumiant▼): increased risk of diverticulitis, particularly in patients with risk factors Use baricitinib with caution in patients with diverticular disease and in those concomitantly treated with medications associated with an increased risk of diverticulitis.	26/8/20	RED drug in 10.1.3	Add link to MHRA DSU.	
Isotretinoin (Roaccutane▼): reminder of important risks and precautions We remind healthcare professionals that isotretinoin should only be used for severe forms of acne resistant to adequate courses of standard therapy with systemic antibacterials and topical therapy.	26/8/20	RED drug in 13.6.2	Add link to MHRA DSU.	
Emollients and risk of severe and fatal burns: new resources available We inform healthcare professionals of the recent campaign to promote awareness of the risk and new resources available to support safe use following previous advice to health and care professionals.	26/8/20	GREEN drugs in 13.2.1	Add link to MHRA DSU plus highlight in CCG MO newsletter to prescribers.	
Letters and drug alerts sent to healthcare professionals in July 2020 A summary of letters and drug alerts recently sent to healthcare professionals • Leuprorelin-containing depot products • Keppra 100 mg/ml Oral Solution (levetiracetam): interim supply of Ireland stock to mitigate supply disruption • Wockhardt UK's Amoxicillin Sodium 250mg, 500mg and 1g Powder for Solution for Injection. • Class 2 Medicines Recall: Mepacrine Hydrochloride 100 mg Tablets (Batch 85641), EL (20)A/27. Issued 2 July 2020. • Class 2 Medicines Recall: Nitrofurantoin 50 mg Tablets, PL 08553/0087, EL (20)A/28. Issued 15 July 2020. • Class 2 Medicines Recall: Ferring Pharmaceuticals Limited, desmopressin nasal spray (all strengths), PL 03194/0024, PL 03194/0090, PL 03194/0056, EL (20)A/29. Issued 15 July 2020. • Class 2 Medicines Recall: Kyowa Kirin Limited, Abstral 200 microgram sublingual tablets, EL (20)A/34. Issued 29 July 2020. • Class 3 Medicines Recall: Accord Healthcare Limited, Irinotecan Hydrochloride Concentrate for Solution for Infusion 20mg/ml (5ml vial), EL (20)A/33. Issued 23 July 2020. • Class 4 Medicines Defect Information: Pfizer Limited, Ecalta 100mg powder for concentrate for solution for infusion, EL (20)A/32. Issued 23 July 2020 • Class 4 Medicines Defect Information: Ennogen Pharma Limited, Trimogal 100mg and 200mg Tablets, EL (20)A/31. Issued 20 July 2020. • Class 4 Medicines Defect Information: Aspar Pharmaceuticals Limited, Ibuprofen 200mg and 400mg tablets packaged in various liveries, EL (20)A/30. Issued 20 July 2020.	26/8/20	For info	No action	
Opioids: risk of dependence and addiction New recommendations following a review of the risks of dependence and addiction associated with prolonged use of opioid medicines (opioids) for non-cancer pain. Before prescribing opioids, discuss with the patient the risks and features of tolerance, dependence, and addiction, and agree together a treatment strategy and plan for end of treatment.	23/9/20	GREEN/AMBER SI drugs in chapter 4.7.2	Add link to MHRA DSU to start of chapter 4.7.2	

Transdermal fentanyl patches for non-cancer pain: do not use in opioid-naive patients Following a review of the risks associated with use of opioid medicines for non-cancer pain, the Commission on Human Medicines (CHM) has recommended that fentanyl transdermal patches are contraindicated in opioid-naive patients in the UK	23/9/20	GREEN drug in chapter 4.7.2	Add link to MHRA DSU plus add note that contra-indicated in opioid-naive patients.
Methotrexate once-weekly for autoimmune diseases: new measures to reduce risk of fatal overdose due to inadvertent daily instead of weekly dosing In autoimmune conditions and some cancer therapies, methotrexate should be taken once a week; however, we continue to receive reports of inadvertent overdose due to more frequent dosing (including daily administration). New measures have been implemented to prompt healthcare professionals to record the day of the week for intake and to remind patients of the dosing schedule and the risks of overdose.	23/9/20	AMBER SC in chapter 1.5.3, 10.1.3, and 13.5.3	Add link to MHRA DSU. Shared Care Guideline already states "The day of the week that the Methotrexate should be taken should also be stated" – need to ensure this specified by GP on prescription.
Insulins (all types): risk of cutaneous amyloidosis at injection site Cutaneous amyloidosis at the injection site has been reported in patients using insulin and this may affect glycaemic control. Remind patients to rotate injection sites within the same body region.	23/9/20	GREEN drugs in chapter 6.1.1	Add link to MHRA DSU to start of chapter 6.1.1
Letters and drug alerts sent to healthcare professionals in August 2020 A summary of letters and drug alerts recently sent to healthcare professionals. • RoActemra (tocilizumab) 162 mg Solution for Injection in Pre-filled Syringe: Interim supply of Irish livery stock to mitigate supply disruption • Fresenius Propoven 2% Emulsion for Injection or Infusion (propofol): Interim Supply of European Stock to Mitigate Supply Disruption • Wockhardt UK's Amoxicillin Sodium 250mg, 500mg and 1g powder for solution for injection: caution and monitoring requirements • Ativan 4mg/ml Solution for Injection (Lorazepam): Temporary supply of a different presentation and changes to the instructions • Class 2 Medicines Recall: Pharmaram Ltd, Clexane 4,000 IU (40mg)/0.4ml Syringes, EL (20)A/37. Issued 4 August 2020. • Class 2 Medicines Recall: Huddersfield Pharmacy Specials MS 19055, Phosphates Solution for Infusion 500ml, EL (20)A/38. Issued 10 August 2020. • Class 2 Medicines Recall: Sanofi Fasturtec 7.5 mg, 1.5 mg/ml powder and solvent for concentrate for solution for infusion, EL (20)A/40. Issued 24 August 2020. • Class 3 Medicines Recall: Accord-UK Ltd, Digoxin Tablets BP 250 micrograms, EL (20)A/35. Issued 3 August 2020. • Class 4 Medicines Defect Information: Crescent Pharma Ltd, SyreniRing 0.120 mg/0.015 mg per 24 hours, vaginal delivery system, EL (20)A/36. Issued 3 August 2020. • Class 4 Medicines Defect Information: SmofKabiven extra Nitrogen Electrolyte Free, EL (20)A/39, PL 08828/0269. Issued 13 August 2020.	23/9/20	For info	No action

Requested formulary amendments	BNF Chapter	Reasoning	Recommended action for APC
Diltiazem 2% rectal ointment – add to formulary as AMBER SI **Commissioning: CCG, in tariff**	1.7.4	Diltiazem 2% cream is AMBER SI but costs £16.35 for 30g whereas the 2% oint cost £11.77for 30g. Both are in Part VIIIB of the Drug tariff.	Add to formulary as AMBER SI as an additional option with sentence to use the most effective product.
Hydrocortisone Colifoam® Foam enema – delete from formulary **Commissioning: CCG, in tariff**	1.5.2	Supply problem since June 2018 - now discontinued (July 2020)	Delete from formulary
Acetic acid 5% solution - add to formulary **Commissioning: CCG, in tariff**	18	Acetic acid 3% (Unlicensed) is on formulary but now the standard CDDFT now get is 5%.	Add to formulary as RED drug
Flecainide 150mg in 15mL injection - add annotation that unlicensed. **Commissioning: CCG, in tariff**	2.3	Is now unlicensed. Needs separate entry for injection.	Add to formulary as RED drug. Add annotation to formulary that unlicensed
Isoprenaline injection 200microgram per mL – add to formulary **Commissioning: CCG, in tariff**	2.7.1	The 2mg in 2ml isoprenaline (both HCL and SO4) has a long term shortage so can the 200microgram per mL be added.	Add to formulary as RED drug.
Morphine 100 microg per ml oral solution– add to formulary **Commissioning: CCG, in tariff**	4.7.2	For use in neonates.	Add to formulary as RED drug.
Sucralfate 1g/5ml oral suspension – add to formulary **Commissioning: CCG, in tariff**	1.3.3	Sucralfate suspension was previously removed from formulary due to issues with supply of the unlicensed product. Licensed version is now available.	Add to formulary as per NoT Formulary position i.e. bile reflux and stomal ulceration = AMBER SI Short term use post Radio Frequency Ablation (RFA) for Barret's Oesophagus and Endoscopic Mucosal Resection = RED
Topiramate – add to formulary for migraine prophylaxis **Commissioning: CCG, in tariff**	4.7.4.2	When did the formulary harmonisation it wasn't included on the CDD or TMGG formulary at that point, it was already on STees formulary but without RAG status. The decision of the group was to add it to the new formulary as amber SI. However subsequently missed off the formulary.	Add to formulary as GREEN drug for migraine prophylaxis with alert around need for adequate contraception if appropriate. No change to AMBER SI status for epilepsy.

Denosumab – review of RAG status for osteoporosis **Commissioning: CCG, in tariff**	6.6.2.2	Currently on formulary as AMBER Shared Care but shared care HAST/STees currently being updated, and no shared care guideline has ever existed in County Durham. Some GPs prescribe in both County Durham and Tees following specialist initiation.	Change to AMBER Specialist Initiation drug from AMBER shared care with updated osteoporosis guideline in place to support this change.
Lift Glucose shot 60ml – add to formulary for hypoglycaemia in Type 1 diabetes **Commissioning: CCG, in tariff**	6.1.4	Request to add to formulary for those patients who are unable to buy this or similar products over the counter for mild hypoglycaemia. Currently, only Glucose 40% oral gel (GlucoGel) is listed on the formulary for moderate hypoglycaemia.	Add to formulary as AMBER Specialist Recommendation for use only when patients unable to buy this or similar products over the counter (i.e. meet one of exceptions to OTC guidance).
New formulary applications	**BNF Chapter**	**Reasoning**	**Recommended action for APC**
Melatonin modified release, Slenyto®, 1mg, 5mg tablets Indicated for the treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient. Slenyto® is currently the only melatonin product licensed for use in children and adolescents.	4.1.1	• May reduce prescribing of the potentially more costly unlicensed Melatonin liquid preparations in this patient population. • Smaller tablet than Circadin - increased likelihood of compliance in those who need a modified release profile but struggle to swallow tablets. • TEWV to produce guideline on use of Slenyto® highlighting when to use each product and cost differential. This guidance will also be shared with paediatric teams in Acute Trusts for them to follow. • Could get challenged if not approved as licensed product for this indication as opposed to using unlicensed Circadin®. • Decision only applies patients meeting licensed indication for Slenyto®.	Approve Slenyto® melatonin 1mg and 5mg modified release tablets in line with licensed indications as AMBER Shared Care only once guidance from TEWV in place and supported by Acute Trust Paediatricians. 1st line for all other indicaitons remains: melatonin 2mg modified release tablets (Circadin®), crushing if needed Rosemont melatonin 5mg/5ml oral solution (alcohol-free and propylene glycol free) - for patients only unable to use crushed tablets.
5 mg of fluorouracil and 100 mg of salicylic acid (SPC) (0.5% 5-FU and 10% salicylic acid) Actikerall® Cutaneous Solution	13.8.1	Requested as an additional option for management of actinic keratosis. Current formulary = Efudfix, Solaraze, and Aldara – all listed as AMBER SI Use supported and included in Primary Care Dermatology Society Actinic Keratosis guideline. Preferred to Efudix in severe lesions.	Add to formulary as GREEN drug, Training and guidance to be given to GPs on how to choose between products. Change Efudfix, Solaraze, and Aldara to GREEN drugs.

Those NICE TAs and decisions with a potential financial impact above the delegated authority limit of the APC will be sent to the CCG Executive meeting for ratification.

ACTION:

- **RDTC to update the online formulary with the approved changes.**
- **RDTC to confirm financial impact of Slenyto® approval and if financial impact above the delegated authority limit of the APC will be sent to the CCG Executive meeting.**

11. New Drug Applications

Melatonin (Slenyto®)

Discussed under Item 10. Application approved by majority vote with 18 members eligible to vote: 10 voted to approve, 1 abstention, 1 spoilt vote.

The RDTC presented information on the current formulary position of Slenyto® elsewhere in the UK as requested at the September 2020 APC.

It was noted that formulary application has now also been received from paediatrics at the STHFT for the licensed indication.

Actikerall®

Discussed under Item 10.

12. NTAG Update

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

- Brolucizumab for wAMD – not approved by NTAG ahead of NICE guidance
- Semaglutide (oral) for type 2 diabetes – approved as an option as per NTAG recommendation.

The APC noted the following reviewed recommendations following the September 2020 NTAG meeting

- Transanal Irrigation Systems (TAIs) for neurogenic bowel dysfunction, chronic constipation, and chronic faecal incontinence – reviewed & no change to recommendation
- Airsonett® laminar flow device for treatment of uncontrolled allergic asthma– reviewed & no change to recommendation

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

13. RMOC Update

The APC noted that the RMOC committees are starting to meet again following a pause due to COVID-19.

The following documents from RMOC South are currently out for consultation and APC members were asked to submit any comments they may have by the deadline:

- Hydroxychloroquine Retinopathy Monitoring
- Buvidal (buprenorphine long-acting injection)

14. CDDFT CSTC Update

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

15. NTHFT D&T Update

No update available as not yet met in November 2020.

16. STHFT D&T Update

Verbal update on November 2020 meeting given including recent Trust formulary approvals which will come to next APC for information/addition to APC formulary as appropriate.

17. Primary Care Prescribing Committee Updates

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

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

18. CD&T APC Transanal Irrigation Guidelines

The final version of the reviewed CD&T APC Transanal Irrigation Guideline following comments received at September 2020 APC was presented to and approved by the APC subject to:

- APC logo being added.
- Clarification added to 'How to Prescribe' section on how and when the GP issues the first prescription.

ACTION:

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

19. Riluzole Shared Care Guideline – reviewed and updated

A reviewed and updated Riluzole Shared Care Guideline was presented to the APC. The following changes were requested before re-submission to January 2020 APC for approval:

- Needs putting into current APC approved shared care template.
- CCG logos need updating.
- Needs to include 'dose needs to be stable at transfer'.
- In Adverse Events section needs further information on:
    - LFTs – how long to monitor weekly LFTs for, and when to contact specialist if still abnormal.
    - WCC - how long to monitor weekly WCC for, and when to contact specialist if still abnormal.

ACTION:

- **RDTC to feedback to STHFT and asked for changes to be made prior to re-submission to January 2020 APC for approval.**

20. NY&VoY Self-monitoring of Blood Glucose Guideline

The recently approved North Yorkshire & Vale of York Self-monitoring of Blood Glucose Guideline was shared with the APC for information as will have some impact on services provided by STHFT in North Yorkshire.

21. CD&T APC Vitamin D Guideline – reviewed and updated

The current local Vitamin D guidelines are due for review. An updated version was presented to and approved by the APC.

ACTION:

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

22. Tapentadol Dose Reduction Guidance for Primary Care

When the formulary status of tapentadol was reviewed in December 2019 it was agreed that that the Chronic pain team at STHFT would prepare a GP information sheet to support appropriate use. There was also a piece of work to be done in primary care to review historic use to make sure use is appropriate in all patients currently prescribed it.
A Tapentadol Dose Reduction Guidance for Primary Care Practitioners has now been prepared and approved by STHFT. It was presented to and approved by the APC subject to adding also for approved on the formulary for inpatient acute pain team use.

ACTION:

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

23. Sativex® Shared Care Guideline

It was agreed at the March 2020 APC meeting that following publication of NICE NG144 in November 2019 that interim position should be that Sativex® for spasticity in MS is RED until shared care in place as per current North of Tyne APC position.
Both Sunderland APC and North of Tyne APC now have shared care guidelines for Sativex® in place and APC is asked to approve their use for patients in APC patch under the care of Sunderland and Newcastle. This was agreed by the APC.
It was note a similar shared care guideline is still to be developed for MS patients under the care of STHFT.

ACTION:

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

24. APC Drug Monitoring Recommendations

A reviewed and updated APC Drug Monitoring Recommendations Guideline for Primary Care was presented to the APC for approval.
It was agreed that as not clear if document has undergone a second check/peer review for accuracy and that is not been via FSG that approval be deferred until January 2020 APC to enable these two things to occur.

ACTION:

- **RDTC to take to FSG for review and confirm with NECS if document undergone a second check/peer review for accuracy.**

25. Northern England Evaluation and Lipid Intensification guideline

A new Northern England Evaluation and Lipid Intensification guideline was presented to and approved the APC.

ACTION:

- **RDTC to arrange for approved version to be added to APC pages of NECS website once available from the regional Lipid Advisory Group.**

Part 5 – Other Items of Business

26. Ketamine in Palliative Care

The APC was informed of correspondence received from the Chair of the regional palliative chair network with regard to ketamine in palliative care and there being not CD&T APC approved shared care guideline. The palliative care network is due to update its palliative care guidelines next year and the development of a regional ketamine in palliative care shared care guideline is being considered. The APC will reconsider its position once updated regional guidelines are available.

27. Shared Care Agreement Across ICS

The APC discussed the letter received about developing and seeking support for the principle of a single shared care guideline agreement across the ICS initially for DMARDs. The APC was supportive of this approach.
It was also agreed that the current expiry of all local DMARD SCPs would be extended for a further three months as they were approaching their current review date.

ACTION:

- **ID to respond to the letter in supportive of the principle of a single shared care**

guideline agreement across the ICS initially for DMARDs.

28. Identifying Lead for Updating Local Atrial Fibrillation Guidelines
It was agreed to identify a lead for updating local Atrial Fibrillation Guidelines outside of the APC meeting.

ACTION:
- **ID/KH/AD to identify a lead for updating local Atrial Fibrillation Guidelines.**

Part 6 – Standing Items (for information only)

29. Formulary Steering Group Minutes – August 2020
For information.

30. TEWV D&T Minutes – July 2020
For information.

31. CDDFT Clinical Standards and Therapeutics Committee Minutes – June 2020
For information.

32. North Tees & Hartlepool Hospitals D&T Minutes – September 2020
For information.

33. South Tees Hospitals D&T Minutes – September 2020
For information.

34. RDTC Horizon Scanning – September & October 2020
For information.

35. NE&C CCG Prescribing Forum Minutes – August 2020
For information.

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

Chairman's Action
Primary Care Guidance for Prescribing and Monitoring Post Bariatric Surgery – final version approved via Chair's Action.

Any Other Business
Nil

Date and time of next meeting:
Thursday 14th January 2021, 9am – 11.30am, virtual meeting via Microsoft Teams tele/videoconference – details to be circulated.