County Durham & Tees Valley Area Prescribing Committee

County Durham and Tees Valley Area Prescribing Committee

Thursday 11th July 2019
9am – 11.30am
Morrison Trust, Morton Park Business Training Centre, Yarm Road, Darlington DL1 4PG

Present

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

Mark Pickering	Chief Finance Officer	Commissioning & Finance Rep	DDES CCG	✓
Rosie England	Chief Pharmacist	NEAS	NEAS	
		Chair of FSG		
Ian Morris	Senior Medicines Optimisation Pharmacist	NECS	NECS	✓
Gavin Mankin	Principal Pharmacist Medicines Management	Professional Secretary	Regional Drug & Therapeutics Centre, Newcastle	✓

In attendance
Angela Dixon, Senior Medicines Optimisation Pharmacist, NECS
Monica Mason, Head of Prescribing Support, Regional Drug & Therapeutics Centre

The meeting was quorate.

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

Part 1

1. Welcome to New APC
The Professional Secretary welcomed members to the first meeting of the new County Durham & Tees Valley APC, and a round of introductions were made.

2. Apologies for absence:
Janet Walker, Rupert Smith, Deborah Giles, Brent Foster, Susan Broughton

3. Declarations of Interest

Declarations of interest:
The Chair reminded subgroup members of their obligation to declare any interest they may have on any issue arising at committee meetings which might conflict with the business of the APC.
Declarations declared by members of the APC are listed in the APC's Register of Interests. The Register is available either via the professional secretary or on the APC website at http://medicines.necsu.nhs.uk/committees/durham-darlington-committees/

Declarations of interest from sub committees:
None declared

Declarations of interest from today's meeting:
Item AOB: Letter from Derwentside PCN – Ian Davidson is GP in Derwentside PCN but agreed could participate in discussion as this was issue relevant to all PCNs and Trusts.

4. Nominations and Appointment of APC Chair
Following a vote by members Dr Ian Davidson was appointed as the new APC Chair and Dr Shafie Kamaruddin as the Vice-Chair.

5. APC Terms of Reference Including Governance Arrangements

The final draft APC Terms of Reference were presented to and approved by the APC subject to the following amendments:

- Section 1 – include HRW CCG and Tees Local Authorities as stakeholders.
- Section 2.2 – remove need to maintain separate NICE TA checklist as formulary website will reflect NICE position and demonstrate compliance with NICE.
- Section 3.4 – clarify that quorum is two-thirds of voting members.
- Confirmation of which CCG committee in the Southern Collaborative that the APC will be accountable to.
- Confirmation from the CCGs as to the financial level of delegated authority the APC will have for approving new drugs and guidelines. Any decisions with a financial impact greater than this will need to be referred to the CCGs for approval.

ACTION:

- **MP to confirm which CCG committee in the Southern Collaborative that the APC will be accountable to.**
- **MP to confirm the financial level of delegated authority the APC will have for approving new drugs and guidelines**
- **RDTC to circulate and published final approved APC Terms of Reference.**

6. How the New APC Will Operate

The RDTC presented an overview of the role and vision of the County Durham & Tees Valley APC, and the roles of the membership.
An overview of the decision making processes of the APC and its Formulary Subgroup was also presented.

7. Outstanding Action Logs

The APC discussed the outstanding action logs from TMGG and CD&D APC.

<u>TMGG</u>

- CMPA – STHFT currently locally at their local product choice and was agreed that this not an issue for new APC.
- Shared care
    - Tinzaparin shared care – still awaiting final version from STHFT. Agreed to add to FSG agenda/APC workplan.
    - Azithromycin shared care – in development and agreed to add to FSG agenda/APC workplan.
- Interface Issues with TEWV – being picked by TEWV.

<u>CD&D APC</u>

- Outpatient Prescribing Requests Form – to be discussed under AOB with reference to recent correspondence from Derwentside PCN.
- Valproate Annual Risk Acknowledgement Form – updated CD&D shared care guideline for valproate on today's agenda. ITEM NOW CLOSED.
- CD&D Paediatric Asthma Guidelines – final amendments completed & added to website. ITEM NOW CLOSED.
- Ciclosporin eye drops – agreed to remove from action log. ITEM NOW CLOSED.
- CD&D APC Atrial Fibrillation Guideline – agreed to add to new workplan and noted STHFT have a draft version going to through their D&T.
- Chapter 11 (Eye) of Formulary – agreed to pick up review of this chapter as part of formulary harmonisation work.
- Lithium Audit in County Durham - audit has been repeated and a report will come to the Sept 2019 APC meeting.
- Hyperprolactinaemia Guideline – no updated to CD&D Drug Monitoring Guidelines required. ITEM NOW CLOSED.
- Prescribing Arrangements for LMWH - The joint QIPP group are now looking at his and

will aim to bring some proposals back to the APC in Sept 2019. It was noted that Tees have shared the work they done already on this.

- Testosterone - Draft a guideline to support the GREEN+ status for testosterone when used for licensed indications is currently in development and the aim is for it to come to the Sept 2019 APC for approval.

Part 2 – Mental Health

8. TEWV Drug & Therapeutics Committee Feedback – May 2019

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

9. Valproate Pregnancy Prevention Programme and TEWV Shared Care (updated)

The TEWV shared care and information on the Valproate Pregnancy Prevention Programme has been updated to reflect the new annual risk acknowledgment form which now allows clinician option of not prescribing contraception if other compelling reasons why patient unlikely to become pregnant. These were circulated for information and were endorsed by the APC.

The APC also discussed how to communicate to community pharmacies that individual patients have an annual risk acknowledgment form for valproate in place. It was agreed where deemed or thought to be necessary to avoid undue patient distress then GPs could communicate with pharmacy that discussion had taken place, and pharmacies could note this in their dispensing systems for future reference.

ACTION:

- **RDTC to arrange for links on formulary website and NECS websites to updated.**

10. TEWV Anxiety Medication Pathway for Adults (updated)

Final updated TEWV D&T approved version to reflect the new NICE guidance on PTSD circulated for information and was endorsed by the APC.

ACTION:

- **RDTC to arrange for links on formulary website and NECS websites to updated.**

11. TEWV Safe Lithium Prescribing and Shared Care

Final updated TEWV D&T approved version circulated for information and was endorsed by the APC.

Changes have been made in response to recent findings from an audit looking at blood sampling for monitoring lithium levels, and in response to other queries from clinical teams in the York area.

ACTION:

- **RDTC to arrange for links on formulary website and NECS websites to updated.**

Part 3 – Formulary Issues

12. Appeals against previous APC decisions

None received.

13. NICE TAs and MHRA Drug Safety Update – April, May & June 2019

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

NICE Technology Appraisal/Guidance Title and date published	Date issued	Current formulary status	Recommended action for APC
TA573: Daratumumab with bortezomib and dexamethasone for previously treated multiple myeloma **Commissioning: NHSE** Daratumumab plus bortezomib plus dexamethasone is recommended for use within the Cancer Drugs Fund as an option for treating relapsed multiple myeloma in people who have had 1 previous treatment. It is recommended only if the conditions in the managed access agreement for daratumumab plus bortezomib plus dexamethasone are followed.	10/04/19	CDD: On formulary in chapter 8.1.5 as a RED drug, with link to TA573. Tees: On formulary in chapter 8.1.5 as a RED drug	No further action.
TA574: Certolizumab pegol for treating moderate to severe plaque psoriasis **Commissioning: CCG** Certolizumab pegol is recommended as an option for treating plaque psoriasis in adults, only if: • the disease is severe, as defined by a total PASI of 10 or more and a DLQI of more than 10 and • the disease has not responded to other systemic treatments, including ciclosporin, methotrexate and phototherapy, or these options are contraindicated or not tolerated and • the lowest maintenance dosage of certolizumab pegol is used (200 mg every 2 weeks) after the loading dosage and • the company provides the drug according to the commercial arrangement. Stop certolizumab pegol at 16 weeks if the psoriasis has not responded adequately. If patients and their clinicians consider certolizumab pegol to be one of a range of suitable treatments, the least expensive should be chosen (taking into account administration costs, dosage, price per dose and commercial arrangements).	17/04/19	CDD: On formulary in chapter 13.5.3 as a RED drug, with link to TA574. Tees: On formulary in chapter 10.1.3 as a RED drug.	Add to formulary as RED drug with link to TA574. No cost impact expected as one several options already included in the formulary.
TA575: Tildrakizumab for treating moderate to severe plaque psoriasis **Commissioning: CCG** Tildrakizumab is recommended as an option for treating plaque psoriasis in adults, only if: • the disease is severe, as defined by a total PASI of 10 or more and a DLQI of more than 10 and • the disease has not responded to other systemic treatments, including ciclosporin, methotrexate and phototherapy, or these options are contraindicated or not tolerated and • the company provides the drug according to the commercial arrangement. Consider stopping tildrakizumab between 12 weeks and 28 weeks if there has not been at least a 50% reduction in the PASI score from when treatment started. Stop tildrakizumab at 28 weeks if the psoriasis has not responded adequately. If patients and their clinicians consider tildrakizumab to be one of a range of suitable treatments, the least expensive should be chosen (taking into account administration costs, dosage, price per dose and commercial arrangements).	17/04/19	CDD: On formulary in chapter 13.5.3 as a RED drug, with link to TA575. Tees: Not on formulary.	Add to formulary as RED drug with link to TA575.

TA576: Bosutinib for untreated chronic myeloid leukaemia (terminated appraisal) **Commissioning: NHSE** NICE is unable to make a recommendation about the use in the NHS of bosutinib for untreated chronic myeloid leukaemia because Pfizer did not provide an evidence submission. The company has confirmed that it does not intend to make a submission for the appraisal because the technology is unlikely to be used at this point in the treatment pathway.	17/04/19	CDD: On formulary in chapter 8.1.5 as a RED drug, with link to TA576. Tees: On formulary in chapter 8.1.5 as a RED drug.	No further action
TA577: Brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma **Commissioning: NHSE** Brentuximab vedotin is recommended as an option for treating CD30-positive cutaneous T-cell lymphoma (CTCL) after at least 1 systemic therapy in adults, only if: • they have mycosis fungoides stage IIB or over, primary cutaneous anaplastic large cell lymphoma or Sézary syndrome and • the company provides brentuximab vedotin according to the commercial arrangement.	24/04/19	CDD: On formulary in chapter 8.1.5 as a RED drug, with link to TA577. Tees: On formulary in chapter 8.1.5 as a RED drug. :	No further action
TA578: Durvalumab for treating locally advanced unresectable non-small-cell lung cancer after platinum-based chemoradiation **Commissioning: NHSE** Durvalumab monotherapy is recommended for use within the Cancer Drugs Fund as an option for treating locally advanced unresectable non-small-cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on at least 1% of tumour cells and whose disease has not progressed after platinum-based chemoradiation only if: • they have had concurrent platinum-based chemoradiation • the conditions in the managed access agreement are followed.	01/05/19	CDD: On formulary in chapter 8.1.5 as a RED drug, with link to TA578. Tees: Not on formulary.	Add to formulary as RED drug with link to TA578.
TA579: Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy **Commissioning: NHSE** Abemaciclib with fulvestrant is recommended for use within the Cancer Drugs Fund as an option for treating hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in people who have had endocrine therapy only if: • exemestane plus everolimus would be the most appropriate alternative and • the conditions in the managed access agreement for abemaciclib with fulvestrant are followed.	08/05/19	CDD: On formulary in chapter 8.1.5 as a RED drug, with link to TA579. Tees: Not on formulary.	Add to formulary as RED drug with link to TA579.
TA580: Enzalutamide for hormone-relapsed non-metastatic prostate cancer **Commissioning: NHSE** Enzalutamide is not recommended, within its marketing authorisation, for treating high-risk hormone-relapsed non-metastatic prostate cancer in adults.	15/05/19	CDD: On formulary in chapter 8.3.4.2 as a RED drug, in line with TA316 and TA377. Link to TA578 already in place. Tees: On formulary in chapter 8.3.4.2 as a RED drug.	No further action

TA581: Nivolumab with ipilimumab for untreated advanced renal cell carcinoma **Commissioning: NHSE** Nivolumab with ipilimumab is recommended for use within the Cancer Drugs Fund as an option for adults with untreated advanced renal cell carcinoma that is intermediate- or poor-risk as defined in the International Metastatic Renal Cell Carcinoma Database Consortium criteria. It is recommended only if the conditions in the managed access agreement for nivolumab with ipilimumab are followed.	15/05/19	CDD: On formulary in chapter 8.2.4 as a RED drug, with link to TA581 Tees: On formulary in chapter 8.1.5 as a RED drug.	Difference in formulary chapter will be addressed during formulary harmonisation.
TA582: Cabozantinib for previously treated advanced hepatocellular carcinoma (terminated appraisal) **Commissioning: NHSE** NICE is unable to make a recommendation about the use in the NHS of cabozantinib for previously treated advanced hepatocellular carcinoma because Ipsen Ltd 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.	24/05/19	CDD: On formulary in chapter 8.1.5 as a RED drug. Tees: On formulary in chapter 8.1.5 as a RED drug.	Add link to TA582 to chapter 8.1.5.
TA583: Ertugliflozin with metformin and a dipeptidyl peptidase-4 inhibitor for treating type 2 diabetes **Commissioning: CCG** Ertugliflozin with metformin and a DPP‑4 inhibitor is recommended as an option for treating type 2 diabetes in adults when diet and exercise alone do not provide adequate glycaemic control, only if: • the disease is uncontrolled with metformin and a DPP‑4 inhibitor, and • a sulfonylurea or pioglitazone is not appropriate. If patients and their clinicians consider ertugliflozin to be 1 of a range of suitable treatments, including canagliflozin, dapagliflozin and empagliflozin, the least expensive should be chosen.	05/06/19	CDD: On formulary in chapter 6.1.2.3 as a GREEN ALTERNATIVE drug. Tees: On formulary in chapter 6.1.2.3 as a GREEN drug.	Add to formulary as GREEN drug with link to TA583. No cost impact expected as one several options already included in the formulary, all of which as similar in price.
TA584: Atezolizumab in combination for treating metastatic non-squamous non-small-cell lung cancer **Commissioning: NHSE** Atezolizumab plus bevacizumab, carboplatin and paclitaxel is recommended as an option for metastatic non-squamous non-small-cell lung cancer (NSCLC) in adults: • who have not had treatment for their metastatic NSCLC before and whose PD-L1 tumour proportion score is between 0% and 49% or • when targeted therapy for epidermal growth factor receptor (EGFR)‑positive or anaplastic lymphoma kinase (ALK)‑positive NSCLC has failed. It is recommended only if: • atezolizumab and bevacizumab are stopped at 2 years of uninterrupted treatment, or earlier if there is loss of clinical benefit (for atezolizumab) or if the disease progresses (for bevacizumab) and • the company provides atezolizumab and bevacizumab according to the commercial arrangements.	05/06/19	CDD: On formulary in chapter 8.2.4 as a RED drug. Tees: On formulary in chapter 8.2.4 as a RED drug.	Add link TA584 to formulary in chapter 8.2.4.

TA585: Ocrelizumab for treating primary progressive multiple sclerosis **Commissioning: NHSE** Ocrelizumab is recommended, within its marketing authorisation, as an option for treating early primary progressive multiple sclerosis with imaging features characteristic of inflammatory activity in adults. It is recommended only if the company provides it according to the commercial arrangement.	12/06/19	CDD: On formulary in chapter 8.2.4 as a RED drug. Tees: On formulary in chapter 8.2.3 as a RED drug.	Add link to TA585 to formulary in chapter 8.2.
TA586: Lenalidomide plus dexamethasone for multiple myeloma after 1 treatment with bortezomib **Commissioning: NHSE** Lenalidomide plus dexamethasone is recommended as an option for treating multiple myeloma in adults only if: • they have had only 1 previous therapy, which included bortezomib, and • the company provides it according to the commercial arrangement	26/06/19	CDD: On formulary in chapter 8.2.4 as a RED drug. Tees: On formulary in chapter 8.2.4 as a RED drug.	Add link to TA586 to formulary in chapter 8.2.4.
TA587: Lenalidomide plus dexamethasone for previously untreated multiple myeloma **Commissioning: NHSE** Lenalidomide plus dexamethasone is recommended as an option for previously untreated multiple myeloma in adults who are not eligible for a stem cell transplant, only if: • thalidomide is contraindicated (including for pre-existing conditions that it may aggravate) or • the person cannot tolerate thalidomide, and • the company provides lenalidomide according to the commercial arrangement	26/06/19	CDD: On formulary in chapter 8.2.4 as a RED drug. Tees: On formulary in chapter 8.2.4 as a RED drug.	Add link to TA586 to formulary in chapter 8.2.4.
NG123: Urinary incontinence and pelvic organ prolapse in women: management	02/04/19	Includes recommendations on use of pharmacological treatments for OAB, including anticholinergics.	Add link to NG123 to chapter 7.
NG124: Specialist neonatal respiratory care for babies born preterm	03/04/19	For info	No further action
NG125: Surgical site infections: prevention and treatment	11/04/19	For info.	Add link to formulary in chapter 5.
NG126: Ectopic pregnancy and miscarriage: diagnosis and initial management	17/04/19	Includes recommendations on methotrexate and misoprostol.	Add link to formulary in chapter 7.
NG127: Suspected neurological conditions: recognition and referral	01/05/19	For info.	No further action.
NG128: Stroke and transient ischaemic attack in over 16s: diagnosis and initial management	01/05/19	Includes recommendations on alteplase, aspirin, and anticoagulants.	Add link to formulary in chapter 2.
NG129: Crohn's disease: management	03/05/19	Includes recommendations on use of steroids, DMARDs and biologics.	Add link to formulary in chapter 1.
NG130: Ulcerative colitis: management	03/05/19	Includes recommendations on use of DMARDs, biologics, and Janus kinase inhibitors.	Add link to formulary in chapter 1.
NG131: Prostate cancer: diagnosis and management	09/05/19	For info.	No further action.

NG132: Hyperparathyroidism (primary): diagnosis, assessment and initial management	23/05/19	Includes recommendations on cinacalcet and bisphosphonates.	Add link to formulary in chapter 6
NG133: Hypertension in pregnancy: diagnosis and management	25/06/19	Includes recommendations on antiplatelets, diuretics and antihypertensives in pregnancy.	Add link to formulary in chapter 2
NG134: Depression in children and young people: identification and management	25/06/19	Includes recommendations on fluoxetine, sertraline and citalopram.	Add link to formulary in chapter 4
Drug Safety Advice	**Date issued**	**Current formulary status**	**Recommended action for APC**
Elvitegravir boosted with cobicistat: avoid use in pregnancy due to risk of treatment failure and maternal-to-child transmission of HIV-1 Pharmacokinetic data indicate exposure of elvitegravir boosted with cobicistat (Genvoya▼, Stribild) is lower during the second and third trimesters of pregnancy than postpartum. Low elvitegravir exposure may be associated with an increased risk of treatment failure and an increased risk of HIV-1 transmission to the unborn child, and therefore elvitegravir/cobicistat should not be used during pregnancy.	16/04/19	CDD: Not on formulary Tees: Not on formulary	No further action
Belimumab (Benlysta▼): increased risk of serious psychiatric events seen in clinical trials Clinical trials, including interim findings from a randomised trial, show an increased risk of depression, suicidal ideation or behaviour, or self-injury in patients with systemic lupus erythematosus receiving belimumab compared with those receiving placebo in addition to standard therapy. Assess patients for these risks before the start of treatment with belimumab and advise them to promptly seek medical attention if they develop new or worsening depression, suicidal ideation or thoughts about injuring themselves.	16/04/19	CDD: On formulary as a RED drug in chapter 10.1.3 with link to DSU. Tees: On formulary as a RED drug in chapter 10.1.3	No further action
Valproate medicines and serious harms in pregnancy: new Annual Risk Acknowledgement Form and clinical guidance from professional bodies to support compliance with the Pregnancy Prevention Programme Ongoing patient survey data suggest that more effort is needed by clinicians to achieve full and timely compliance with the valproate Pregnancy Prevention Programme and meet the goal to rapidly reduce and eventually eliminate the harms of valproate in pregnancy in view of its serious teratogenicity. We have updated the Annual Risk Acknowledgement Form, which should be used during annual specialist review of all women and girls of childbearing potential on valproate medicines (irrespective of indication). Specialists should comply with guidance given on the form if they consider the patient is not at risk of pregnancy, including the need for regular review in case her risk status changes.	16/04/19	CDD: On formulary as GREEN in chapters 4.2.3, 4.7.4.2 and 4.8.1. On formulary as AMBER in same chapters for use in girls and women of child-bearing potential, with link to DSU. Tees: On formulary as GREEN PLUS in chapters 4.2.3 and 4.8.1	No further action.

Yellow fever vaccine (Stamaril) and fatal adverse reactions: extreme caution needed in people who may be immunosuppressed and those 60 years and older We have recently received 2 reports of fatal adverse reactions to the yellow fever vaccine (Stamaril). Due to an increased risk of life-threatening reactions, the vaccine must not be given to anyone with a medical history of thymus dysfunction or who is immunosuppressed. In addition, extreme caution must be used and a careful risk assessment conducted before vaccination of people aged 60 years and older due to a substantially increased risk of such adverse reactions in this age group.	16/04/19	CDD: On formulary as GREEN, with link to DSU. Tees: Not on formulary. Travel vaccines are included on the Do Not Prescribe list.	No further action.
Letters and drug alerts sent to healthcare professionals in March 2019 Letters: • Xeljanz▼ (tofacitinib): Increased risk of pulmonary embolism and mortality in rheumatoid arthritis patients receiving 10 mg twice daily in a clinical trial. • Ranitidine 150 mg tablets: Batch number and expiry date prompts 'LOT' and 'EXP' printed in German on outer (carton) packaging • Nulojix (belatacept): Update on the temporary restriction in supply (initiated in March 2017) • Fluoroquinolone antibiotics: risk of disabling, long-lasting and potentially irreversible side effects – new restrictions on prescribing for ciprofloxacin, levofloxacin, moxifloxacin, and ofloxacin for safety reasons • Genvoya▼ (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide), Stribild▼ (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil), Tybost (cobicistat): Increased risk of treatment failure and increased risk of mother-to-child transmission of HIV infection due to lower exposure of elvitegravir and cobicistat during the second and third trimesters of pregnancy • Belimumab (Benlysta▼): Increased risk of serious psychiatric events (depression, suicidal ideation or behaviour, or self-injury)	16/04/19	For info	For info
Magnesium sulfate: risk of skeletal adverse effects in the neonate following prolonged or repeated use in pregnancy Maternal administration of magnesium sulfate for longer than 5–7 days in pregnancy has been associated with skeletal adverse effects and hypocalcaemia and hypermagnesemia in neonates. If use of magnesium sulfate in pregnancy is prolonged or repeated, consider monitoring of neonates for abnormal calcium and magnesium levels and skeletal adverse effects.	17/05/19	CDD: On formulary as a RED drug in chapters 2.3, 3.1 and 9.5.1, with link to DSU. Tees: Not on formulary	No further action.
Tofacitinib (Xeljanz▼): restriction of 10 mg twice-daily dose in patients at high risk of pulmonary embolism while safety review is ongoing Following observation in a clinical study of an increased risk of pulmonary embolism and overall mortality with tofacitinib 10 mg twice-daily in rheumatoid arthritis, a safety review has started and new contraindications introduced. The 10 mg twice-daily dose of tofacitinib (authorised for ulcerative colitis) must not be used in patients at high risk of pulmonary embolism.	17/05/19	CDD: On formulary as a RED drug in chapters 1.5.3 and 10.1.3, with link to DSU. Tees: On formulary as a RED drug in chapter 10.1.3.	No further action.

Lemtrada (alemtuzumab) and serious cardiovascular and immune-mediated adverse reactions: new restrictions to use and strengthened monitoring requirements While an urgent EU safety review evaluates reports of serious cardiovascular events and immune-mediated reactions, including autoimmune hepatitis, the use of alemtuzumab (Lemtrada) has been restricted and strengthened requirements have been introduced to monitor vital signs and liver function before and during treatment. All patients on alemtuzumab for multiple sclerosis should be alerted to these risks and what to do if symptoms occur.	17/05/19	CDD: On formulary as a RED drug in chapter 8.2.3, with link to DSU. Tees: On formulary as a RED drug in chapter 8.2.3	No further action
Letters and drug alerts sent to healthcare professionals in April 2019 Letters: • Alemtuzumab (Lemtrada): Restriction of use due to serious safety concerns • Erelzi▼ (etanercept) 25 mg and 50 mg pre-filled syringes: limited number of batches with French syringe labels • Selenase (sodium selenite pentahydrate): similarity of oral and parenteral preparations; risk of dispensing errors	17/05/19	For info	For info
Direct-acting oral anticoagulants (DOACs): increased risk of recurrent thrombotic events in patients with antiphospholipid syndrome A clinical trial has shown an increased risk of recurrent thrombotic events associated with rivaroxaban compared with warfarin, in patients with antiphospholipid syndrome and a history of thrombosis. Other direct-acting oral anticoagulants (DOACs) may be associated with a similarly increased risk.	19/06/19	CDD: All DOACs on formulary as GREEN drugs in chapter 2.8.2 Tees: All DOACs on formulary as GREEN drugs in chapter 2.8.2	Add link to DSU to chapter 2.8.2
GLP-1 receptor agonists: reports of diabetic ketoacidosis when concomitant insulin was rapidly reduced or discontinued Diabetic ketoacidosis has been reported in patients with type 2 diabetes on a combination of a GLP-1 receptor agonist and insulin who had doses of concomitant insulin rapidly reduced or discontinued. GLP-1 receptor agonists are not substitutes for insulin, and any reduction of insulin should be done in a stepwise manner with careful glucose self-monitoring. Abrupt discontinuation or reduction in insulin doses can lead to poor glycaemic control, with a risk of diabetic ketoacidosis.	19/06/19	CDD: Dulaglutide, liraglutide and lixisenatide on formulary as GREEN PLUS drugs in chapter 6.1.2.3. Exenatide not on formulary. Tees: All GLP-1 receptor agonists on formulary in chapter 6.1.2.3 as GREEN or GREEN PLUS drugs.	Add link to DSU to chapter 6.1.2.3.
Lartruvo▼ (olaratumab): withdrawal of the EU marketing authorisation due to lack of efficacy The ANNOUNCE study failed to show clinical efficacy for olaratumab in its current indication of advanced soft tissue sarcoma and the benefit risk balance is therefore now considered negative. No new patients should be started on olaratumab therapy.	19/06/19	CDD: on formulary in chapter 8.1.5 as a RED drug. Tees: on formulary in chapter 8.2.3 as a RED drug.	Remove olaratumab from formulary.

Oral retinoid medicines▼: revised and simplified pregnancy prevention educational materials for healthcare professionals and women New prescriber checklists, patient reminder cards, and pharmacy checklists are available to support the Pregnancy Prevention Programme in women taking acitretin, alitretinoin, and isotretinoin. Advice about the risk of neuropsychiatric reactions has been made consistent for all oral retinoid medicines.	19/06/19	CDD: Alitretinoin on formulary in chapter 13.5.1, acitretin in chapter 13.5.2, and isotretinoin in chapter 13.6.2. All as RED drugs. Tees: Acitretin and alitretinoin on formulary in chapter 13.5 as RED drugs. Isotretinoin on formulary is on formulary in chapter 13.6 as a RED drug.	Add link to DSU to chapter 13.
Letters and drug alerts sent to healthcare professionals in May 2019 • Tofacitinib (Xeljanz▼): letter to provide additional detail on safety concerns • Epanutin (phenytoin) oral solution shortage – letter and alert • Trisenox (arsenic trioxide, 1 mg/ml concentrate for solution for infusion): replacement with import of arsenic trioxide injection 1 mg/ml (Phenasen) into the UK during the supply shortage • Lapatinib (Tyverb): important update to the therapeutic indication and Summary of Product Characteristics • Apixaban (Eliquis), dabigatran etexilate (Pradaxa), edoxaban (Lixiana▼) and rivaroxaban (Xarelto▼) are not recommended in patients with antiphospholipid syndrome due to possible increased risk for recurrent thrombotic events • Lartruvo▼ (olaratumab): withdrawal of the EU marketing authorisation due to lack of therapeutic efficacy	19/06/19	For info: Alitretinoin on formulary in chapter 13.5.1 as RED drugs	For info
NHS Patient Safety Alerts	**Date issued**	**Current formulary status**	**Recommended action for APC**
Assessment and management of babies who are accidentally dropped in hospital A resource Patient Safety Alert has been issued to help organisations ensure any injuries to an accidentally dropped baby are detected and treated as quickly as possible	09/05/19	For info	No further action.

ACTION:

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

14. Harmonisation of CD&D and Tees Formularies into one Single Formulary Chapter 1-5

A small working group of pharmacists from APC stakeholder organisations has met to discuss and make a recommendation for the new harmonise formulary for those drugs where differences currently exist between CD&D Formulary and Tees Formularies in BNF Chapters 1-5.

The APC approved the recommended action to harmonise the formulary where differences currently exist between CD&D Formulary and Tees Formularies in BNF Chapters 1-5.

Those drugs highlighted in red type are where further work is required before a final recommendation can be made to the APC for approval.

Drugs where particular input from APC is required are:

- Melatonin – should it be AMBER Shared Care or could it be changed to Amber Specialist Initiation as no significant monitoring required – agreed to remain AMBER Shared Care as specialist input required to review continued need for therapy on a regular basis.

- Cabergoline - should it be AMBER Shared Care or could it be changed to Amber Specialist Initiation (Ergot-derived agonists have been associated with pulmonary, retroperitoneal, pericardial & cardiac valve fibrotic reactions) – agreed should be AMBER Shared Care.
- Pergolide - should it be AMBER Shared Care or could it be changed to Amber Specialist Initiation (Ergot-derived agonists have been associated with pulmonary, retroperitoneal, pericardial & cardiac valve fibrotic reactions) - agreed should be AMBER Shared Care.
- Bromocriptine should it be AMBER Shared Care or could it be changed to Amber Specialist Initiation (Ergot-derived agonists have been associated with pulmonary, retroperitoneal, pericardial & cardiac valve fibrotic reactions) - agreed should be AMBER Shared Care.

ACTION:

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

15. New Drug Applications

Meformin in PCOS

Formulary application from by NTHFT for use in polycystic ovary syndrome in patients not receiving fertility treatment from secondary care was approved as an Amber Specialist initiation / recommendation drug. Noted already on CD&D and STHFT formularies for this indication.

Magnesium Sulphate Pre-filled Syringes

A decision on approving Magnesium Sulphate Pre-filled Syringes as RED drug for management of pre-eclampsia and eclampsia in pregnancy following an application from STHFT was deferred as not yet been discussed at STHFT D&T.

Fresubin thickened level 2

A decision on approving of Fresubin thickened level 2 following an application from STHFT to be used to thicken oral fluids in to aid swallowing and prevent choking in patients with swallowing difficulties e.g. stroke patients was deferred as not yet been discussed at STHFT D&T.

ACTION:

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

16. NTAG Update

The current NTAG workplan was circulated to the group for information.

17. RMOC Update

The following updates from RMOC were circulated to the group for information:

- RMOC Newsletter Issue 3 – 2019
- RMOC Newsletter Issue 4 - 2019
- RMOC Newsletter Issue 5 – 2019
- RMOC Position Statement – Rarely Used and Urgent Medicines

18. CDDFT CSTC Update

A verbal update on the last meeting of CDDFT CSTC was provided.

19. NTHFT D&T Update

A verbal update on the last meeting of NTHFT D&T was provided. Noted that local guidance on testing strips for diabetes requires review.

20. STHFT D&T Update

A verbal update on the last meeting of NTHFT D&T was provided. Applications for ferric maltol for anaemia and alteplase for unblocking catheters had been discussed.

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

21. Shared Care Guidelines for Approval

County Durham Azathioprine (updated)

An updated azathioprine shared care guideline for County Durham & Darlington was presented and approved by the APC. It ensures recommendations regarding monitoring of patients prescribed azathioprine are in line with national guidance.

South Tees Melatonin

The APC discussed a draft SCG for Melatonin for use by the paediatric team at STHFT. It suggested that STHFT look to adopt the existing SCG for melatonin from TEWV so that there is one SCG in use across the geographical area covered by the APC

ACTION:

- **RDTC to arrange for updated azathioprine shared care guideline to be added APC pages of NECS website.**
- **CW to shared TEWV Melatonin shared care guideline with HJ for discussion at STHFT D&T.**

22. Paediatric Asthma Guidelines – adoption by Tees

The Tees respiratory network have asked to adopt the Durham APC paediatric asthma guidelines for use in HaST and South Tees with no changes and this was approved by the APC.

ACTION:

- **RDTC to arrange for Paediatric Asthma Guidelines to updated with new APC logo and add to APC pages of NECS website.**

Part 5 – Other Items of Business

23. Development of APC Workplan

APC members were asked to consult with their respective organisations and suggest topics to include in the workplan for the APC for the next 12 months. Suggestions received will be discussed at the Sept 2019 APC meeting. Topics suggested to date include updating local Atrial Fibrillation Guidelines and guidance on responsibility/commissioning arrangements for prescribing low molecular weight heparins.For the APC to discuss and agree a workplan for the next 12 months based on

ACTION:

- **APC members were asked to consult with their respective organisations and suggest topics to include in the workplan for the APC for the next 12 months.**

24. Opioid Statement

The APC discussed the draft County Durham and Tees Valley APC Position Statement on Prescribing in Persistent Pain based on similar statement being produced in Sunderland & South Tyneside.

Across the CCGs work has been ongoing to try and reduce prescribing of these medications in order to increase patient safety – this has included the development of guidelines on opioid prescribing and prescribing in neuropathic pain, prescriber education, producing supporting resources for GPs and including practice level targets into the primary care funding schemes. GPs have however requested a stronger statement from the CCGs to provide extra support to prescribers via the Local Prescribing Group Meetings.

It was agreed that further consultation was required across County Durham and Teesside on the draft before a final version was brought back to September 2019 APC for approval.

ACTION:

- **KH to consult further across County Durham and Teesside on the draft APC Position Statement on Prescribing in Persistent Pain.**
- **CJ to seek comments from Public Health.**

Part 6 – Standing items (for information only)

25. Formulary Steering Group Minutes
None available as group has not yet met.

26. TEWV D&T Minutes March 2019
For information.

27. CDDFT Clinical Standards and Therapeutics Committee Minutes
Not yet available.

28. North Tees & Hartlepool Hospitals D&T Minutes – May 2019
For information.

29. South Tees Hospitals D&T Minutes
Not yet available.

30. NTAG Minutes February 2019
For information.

31. NTAG Annual Report 2018/19
For information.

32. RDTC Horizon scanning – June 2019
For information.

33. NE&C CCG Prescribing Forum Minutes
Not yet available.

34. NEAS Medicines Group Minutes – March 2019
For information.

Chairman's Action

Outpatient Treatment Recommendations – correspondence from Derwentside PCN

The APC discussed the letter sent by Derwentside PCN to local Trusts regarding GP practices in Derwentside ceasing to accept Outpatient Treatment Recommendation Forms from Aug 2019. The APC noted that other PCNs were currently considering their position, and that CDDFT were meeting to discuss their response. The LMC have been and continue to work with CDDFT on this issue. A previous audit in Tees for outpatient treatment recommendation forms was done and it was agreed to share the results. It was agreed that work was needed to explore the issues that have been addressed, to see what position other PCNs will take, and to see currently if this mainly a County Durham issue.

Any Other Business
Nil

Date and time of next meeting:
Thursday 12th September 2019, 9am – 11.30am, Memorial Hall Boardroom at Darlington Memorial Hospital.