County Durham and Darlington Area Prescribing Committee

Thursday 5th May 2016
11.30am – 2.30pm
Board Room, Appleton House

Present

Dr Ian Davidson, Director of Quality & Safety, North Durham CCG (chair)
Dr Catherine Harrison, GP Prescribing Lead, DDES CCG
Dr Esther Sheard, GP Prescribing Lead, North Durham CCG
Dr Peter Forster, GP Prescribing Lead, DDES CCG (from item 3c)
Mike Leonard , Directorate Pharmacist, TEWVFT (representing Paul Walker)
Claire Jones, Public Health Pharmacist, Durham County Council
Gavin Mankin, RDTC Representative (Professional Secretary)
Dan Newsome, Medicines Optimisation Pharmacist, NECS
Joan Sutherland, Medicine Optimisation Lead Pharmacist, North Durham CCG
Kate Huddart Senior Pharmaceutical Advisor, DDES CCG
Graeme Kirkpatrick, Chief Pharmacist, CD&DFT
Chris Williams, Chief Pharmacist, TEWV FT
Beverley Walton, Lead Clinical Pharmacist, CD&DFT
Sarah McGeorge, Non-Medical Prescriber, TEWVFT
Dr Robin Mitchell, Deputy Medical Director, CD&DFT
Rob Pitt, LPC representative

In attendance
Dr Patrick Ojechi, Diabetes Lead GP, North Durham CCG – for item 4b
Dr Praveen Partha, Consultant, CD&DFT – for item 4b

The meeting was quorate.

Part 1 (11.30)

1a Apologies for absence:
Melanie Robinson, Jo Linton, Martin Jones, Alwyn Foden

The group noted that Betty Hoy had resigned and a replacement is currently being sought. The Chair has written to her to thank for her service to the committee since its formation.

1b Declarations of Interest
No declarations of interest relating to the agenda were raised.

1c Minutes of the previous APC meeting held 3rd March 2016
The minutes were accepted as a true and accurate record.

1d Matters Arising/Action Log

Actions from March 2016 meeting not on the agenda or action log
Nil

Action Log
TEWV Depression Pathway Medication Algorithm
Has now been added to website. ITEM NOW CLOSED.

Alcohol 3-way Agreement
Primary care in County Durham has been notified of withdrawal of Alcohol 3-way agreement. Formulary has been updated to state that drugs for alcohol dependence are now RED in County Durham but remains unchanged for Darlington as the GPs are commissioned in Darlington to prescribe these drugs. ITEM NOW CLOSED.

Ciclosporin Eye Drops
Ophthamolgists have been contacted and they suggest Green+ status as per Sunderland. The number of patients likely to be low and all patients will be under regular review of secondary care. No other specialist monitoring required.
After discussion the APC still felt AMBER status was more appropriate due to concerns about inappropriate initiation in primary care and to ensure patients remain under regular review from secondary care

ACTION:

- **BW to have further discussions with Ophthalmologists on suggested AMBER status for ciclosporin eye drops.**

Methotrexate and Hydroxychloroquine Shared Care Guidelines
Have now been added to website. ITEM NOW CLOSED.

High Cost Drugs Group Terms of Reference
Have now been approved via Chair's Action. ITEM NOW CLOSED.

Patient Representative Role on APC
Job description has been updated with suggested changes. ITEM NOW CLOSED.

Diabetes Prescribing Guidelines
On today's agenda.

Erectile Dysfunction Guidelines
On today's agenda for final approval.

FATS7 – A Strategy for the use of Cholesterol Lowering Drugs across the NE&Cumbria
Confirmed that NESCN will produce a generic regional version of this guideline and forward to us once available.

Historic Actions

Subcutaneous methotrexate
GK continues to explore the various homecare options and waste collection options with the aim of going out to tender/having a process in place soon. GK is to form a task & finish group to include representatives from contracting to take this forward.

Neuropathic pain audit
CDDFT have met with their clinicians and are still finalising a guideline to define appropriate course length.

Letrozole and DEXA scans
DEXA scans associated with aromatase inhibitors will now be exclusively requested by secondary care. This is to be confirmed in writing prior to GPs being notified

ACTION:

- **GK to get confirmation in writing that in future secondary care will be responsible for all DEXA scans associated with aromatase inhibitors.**

Food supplement contracting issues
The NECS Provider Management Team it to take on a proposal to re-procure the food supplement contract from November 2016. As a result the current pathway does not need to be amended at this stage. ITEM NOW CLOSED.

Camcolit 250® brand name change
Primary care still need to scope how many patients are currently receiving lithium outside of current shared care guidelines.

Psychotropic prescribing: peri-pregnancy and in women of child bearing age
Has now been added to website. ITEM NOW CLOSED.

Declarations of Interest
CDDFT membership vacancies still to be followed up with Medical Directors Office.

CD&D Drug Monitoring Document
This has now been approved via Chair's Action and added to the website. ITEM NOW CLOSED.

NICE NG5 – Medicines Optimisation – key priorities for implementation
A subgroup has now been formed and will meet for the first time next week.
The baseline assessments are also be raised at local CCG Quality Review Groups.

Use of patient decision aids to discuss anticoagulant choice
Awaiting creation of NICE NG5 – Medicines Optimisation subgroup.

Osteoporosis Guideline
Work still in progress.

Part 2 – Mental Health (12.00)

2a TEWV Drug & Therapeutics Committee Feedback – March 2016

CW presented to the APC a briefing report highlighting the main issues discussed at the recent TEWV D&T.
The following issues were highlighted to the group:

- Citalopram/Escitalopram – monitoring magnesium levels – guidance has now been issued and included in the updated local drug monitoring document.
- Methylphenidate XL – it has been agreed to recommend that the brand with the lowest current acquisition cost should be used (this is currently Xenidate XL®) and the local shared care guidelines will be updated to reflect this.
- Methohexitone for ECT – an application to use methohexitone instead of propofol as the preferred anaesthetic agent for ECT was not approved. The basis of this decision was that methohexitone is unlicensed in the UK and the published evidence suggests propofol is no less effective.

2b Challenging Behaviour in People with Cognitive Impairment

This guidance has been produced in South Tees and was shared with the APC for local adoption.
The guideline was approved by the group for adoption locally and circulation to GPs within County Durham & Darlington and also within CDDFT.

ACTION:

- **GM to arrange for document to be added to CD&D pages of NECS website.**
- **GK to take document to CDDFT CTSC for adoption within secondary care.**

Part 3 – General (12.30)

3a Appeals against previous APC decisions
None received.

3b Update from Formulary Subgroup for May 2016 APC
This was presented to the group and the following actions were taken by the APC:

Formulary Updates since March 2016 APC for approval including RAG changes
Approved with suggested changes to RAG recommendation as follows:

NICE Topic Decision	Date Issued	Formulary status	Action taken following Feb 2016 FSG meeting
NG34 Sunlight exposure: risks and benefits	28.2.2016	n/a	No action required as contains no drugs.
NG35 Myeloma: diagnosis and management	28.2.2016	Chemo drugs all listed as RED in Chapter 8.	Include link in the formulary at start of Chapter 8.
NG36 Cancer of the upper aerodigestive tract: assessment and management in people aged 16 and over	28.2.2016	n/a	No action required as contains no drugs.
NG37 Fractures (complex): assessment and management	28.2.2016	n/a	No action required as contains no drugs.
NG38 Fractures (non-complex): assessment and management	28.2.2016	Analgesics listed as GREEN in section 4.7	No action required.
NG39 Major trauma: assessment and initial management	28.2.2016	Tranexamic acid listed as GREEN in section 2.11	No action required.
NG40 Major trauma: service delivery	28.2.2016	n/a	No action required as contains no drugs.
NG41 Spinal injury: assessment and initial management	28.2.2016	Analgesics listed as GREEN in section 4.7	Include link in the formulary
NG42 Motor neurone disease: assessment and management	28.2.2016	Quinine in 10.2.2 as green alt. Tizanidine in 10.2.2 as green+. Dantrolene in 10.2.2 as green alt. Gabapentin in 4.7.3 as green alt. Baclofen in 10.2.2 as Green. Glycopyrrolate not listed (N.B. unlicensed)	Include link in the formulary at start of Chapter 4.
NG43 Transition from children's to adults' services for young people using health or social care services	28.2.2016	n/a	No action required as contains no drugs.
TA383 TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis 1.1 Adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are recommended, within their marketing authorisations, as options for treating severe active ankylosing	28.2.2016	Listed in section 10.1.3 as a RED drugs	No action required except to add link to formulary.

spondylitis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. Infliximab is recommended only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop. 1.2 Adalimumab, certolizumab pegol and etanercept are recommended, within their marketing authorisations, as options for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. 1.3 The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen. 1.4 The response to adalimumab, certolizumab pegol, etanercept, golimumab or infliximab treatment should be assessed 12 weeks after the start of treatment. Treatment should only be continued if there is clear evidence of response, defined as: a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more. 1.5 Treatment with another tumour necrosis factor (TNF)-alpha inhibitor is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first TNF-alpha inhibitor, or whose disease has stopped responding after an initial			

response. 1.6 When using BASDAI and spinal pain VAS scores, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the responses to the questionnaires, and make any adjustments they consider appropriate			
TA384 Nivolumab for treating advanced (unresectable or metastatic) melanoma Nivolumab as monotherapy is recommended, within its marketing authorisation, as an option for treating advanced (unresectable or metastatic) melanoma in adults.	28.2.2016	Not listed in section 8.1	Suggest add to formulary as a RED drug and include link.
TA385 Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia 1.1 This guidance should be used with NICE's guidelines on cardiovascular disease: risk assessment and reduction, including lipid modification and familial hypercholesterolaemia: identification and management. 1.2 Ezetimibe monotherapy is recommended as an option for treating primary (heterozygous‑familial or non‑familial) hypercholesterolaemia in adults in whom initial statin therapy is contraindicated. 1.3 Ezetimibe monotherapy is recommended as an option for treating primary (heterozygous‑familial or non‑familial) hypercholesterolaemia in adults who cannot tolerate statin therapy (as defined in section 1.6). 1.4 Ezetimibe, co‑administered with initial statin therapy, is recommended as an option for treating primary (heterozygous‑familial or non‑familial) hypercholesterolaemia in adults who have started statin therapy when: serum total or low‑density lipoprotein (LDL) cholesterol concentration is not appropriately controlled (as defined in section 1.7) either after appropriate dose titration of initial statin therapy or because dose titration is limited by intolerance to the initial statin therapy (as defined in section 1.6) and a change from initial statin therapy to an alternative statin is being considered. 1.5 When prescribing ezetimibe	28.2.2016	Listed in section 2.12 as Green alternative drug	No action required except to add link to formulary. Noted that link in local lipid guideline will also need updating.

co-administered with a statin, ezetimibe should be prescribed on the basis of lowest acquisition cost. 1.6 For the purposes of this guidance, intolerance to initial statin therapy is defined as the presence of clinically significant adverse effects that represent an unacceptable risk to the patient or that may reduce compliance with therapy. 1.7 For the purposes of this guidance, appropriate control of cholesterol concentrations should be based on individual risk assessment according to national guidance on managing cardiovascular disease in the relevant populations.			
TA289 (review) Ruxolitinib for disease-related splenomegaly or symptoms in adults with myelofibrosis	30.3.2016	Listed in section 8.1.5 as a RED drug	Include link in formulary.
MHRA Drug safety advice	**Date Issued**	**Formulary status**	**Action taken following Feb 2016 FSG meeting**
Valproate and of risk of abnormal pregnancy outcomes: new communication materials Children exposed to valproate in utero are at high risk of developmental disorders and congenital malformations.	Feb 2016	Listed in section 4.2.3 and 4.8 as a GREEN drug	Include link in formulary.
Spironolactone and renin-angiotensin system drugs in heart failure: risk of potentially fatal hyperkalaemia Monitoring of blood electrolytes is essential in patients coprescribed a potassium-sparing diuretic and an angiotensin converting enzyme inhibitor (ACEi) or an angiotensin receptor blocker (ARB) for heart failure.	Feb 2016	Listed in section 2.2.3 as a GREEN+ drug	Include link in formulary.
Trametinib (Mekinist▼): risk of gastrointestinal perforation and colitis Use trametinib, authorised either as monotherapy or combined with dabrafenib, with caution in patients with risk factors for gastrointestinal perforation.	March 2016	Not in listed	No action required.

Letters sent to healthcare professionals in January 2016 A summary of letters sent to healthcare professionals in January 2016 to inform of safety for: • Fingolimod (Gilenya▼): risks related to effects on the immune system • Erlotinib (Tarceva): first-line maintenance indication now restricted to patients with a tumour that has an EGFR-activating mutation	Feb 2016	Listed in section 8.2.4 as RED drug. Listed in section 8.1.5 as RED drug.	Include link in formulary to Fingolimod and Erlotinib letters
Letters sent to healthcare professionals in February 2016 A summary of letters sent to healthcare professionals in February 2015 to inform of safety for: • Medicines containing valproate and the risk of abnormal pregnancy outcomes: new communication materials	March 2016	Listed in section 4.2.3 and 4.8 as a GREEN drug	Already actioned (see above)
NTAG recommendation	**Date Issued**	**Formulary status**	**Action taken following April 2016 meeting**
See agenda item 3e			
Requested formulary amendments	**BNF Chapter**	**Reasoning**	**Action taken following April 2016 meeting**
Hyaluronic acid – for osteoarthritis	10.4	Use not recommended in NICE CG177 Feb 2014. Listed as Green drug but treated as RED drug and now no longer stocked in clinical areas by CDDFT.	Change to Not Approved.
Nefopam	4.7.1	Branded nefopam, Acupan®, came off patent at the end of 2015 year. Currently, the only generic available is considerably more expensive than the previous, branded product. Not included in any local pain guidelines and pain team no longer actively recommending.	Change to Not Approved from Green alternative. This will apply to new patients only.

ACTION:

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

3c New Drug Applications

Guanfacine

A new drug application for Guanfacine was presented to and approved by the APC.

It was agreed that should be classed as an AMBER drug to be used to be used for Treatment

of Attention Deficit Hyperactivity Disorder in children and adolescents 6-17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective AND in those whom Atomoxetine is not suitable, not tolerated or has been shown to be ineffective.

ACTION:

- **GM to update the online formulary with the approved change.**
- **CW to produce a shared care guideline for approval.**

Invicorp®

A new drug application for Invicorp® presented the APC.

It was agreed that should be classed as NOT APPROVED. This was because of limited trial data versus existing treatment choices (e.g. alprostadil), use of the drug does not appear to be widespread in the UK currently, and lack of reviews from other local or national appraisal groups e.g. SMC, AWMSG.

ACTION:

- **GM to update the online formulary to show it is a "not approved drug"**

Nutilis Clear Thickener

A new drug application for Nutilis Clear Thickener was presented to and approved by the APC as replacement for Nutilis, and to be the thickening agent of choice locally.

It was agreed that should be classed as a GREEN drug.

ACTION:

- **GM to update the online formulary with the approved change.**
- **DN to work with SALT team to produce a guide for GPs to support switch to Nutilis Clear as thickening agent of choice.**

3d Shared Care Guidelines for Approval

An updated version of the riluzole shared care protocol to include the new licensed oral suspension was presented to and approved by the group.

ACTION:

- **GM to arrange for final versions of Riluzole Shared Care Guideline to be added to CD&D pages of NECS website.**

3e NTAG Update

A verbal update on the NTAG recommendations following their November 2015 meeting was given.

- Etanercept Biosimilar 50mg (Benepali®▼, Biogen) - The Northern (NHS) Treatment Advisory Group recommends the use of etanercept biosimilar Benepali® as an option for use in adults where the originator product (Enbrel®) would normally be prescribed.
- e-Voke® (Nicovations Ltd) electronic inhaler - The Northern (NHS) Treatment Advisory Group does not recommend the use of e-Voke® as a stop smoking aid on the NHS.
- Transanal irrigation (TAI) systems (Peristeen®, Aquaflush®, Irypump® S and QuFora®) for neurogenic bowel dysfunction, chronic constipation and chronic faecal incontinence - The Northern (NHS) Treatment Advisory Group recommends the use of transanal irrigation as an option for treatment when all other treatment options have failed or proved ineffective and if initiated and monitored by a specialist.

The formulary website will be updated accordingly with the recommendations for Etanercept Biosimilar and E-voke e-cigarette. The RAG status of etanercept will remain the same and E-voke e-cigarette will be given a "not approved" RAG status.

3f Durham APC Guideline Template

A suggest template for the format of CD&D APC guidelines was presented to the group. After discussion it was felt that a checklist for guidelines being presented to the APC for approval accompanied by a standard footer rather than an actual document template would be more appropriate. This was because each stakeholder organisation need comply with the policies for the format of guidelines within their own organisations.

ACTION:

- **GM to draft a suggested checklist for guidelines being submitted to APC for approval and a proposed standard footer.**

3g APC Annual Report 2015/16

This was presented to and approved by the group with the addition of section on the group's declarations of interest policy.

ACTION:

- **GM to arrange for document to be added to CD&D pages of NECS website once a section on Declarations of Interest added.**

3h Annual Review of Terms of Reference

The APC Terms of Reference were reviewed approved by the group for a further 12 months with the addition of a section on declarations of interest.
The group noted that work is underway to recruit a new patient representative and also new consultant membership from CDDFT including the new chair of the CDDFT Clinical Standards and Therapeutics Committee.

ACTION:

- **ID/GM to meet with potential new patient representatives to APC to identify a suitable candidate**.
- **ID/GM to approve via Chair's action and arrange for document to be added to CD&D pages of NECS website once section on Declarations of Interest added.**

3i CDDFT Update April 2016

An update on hospital only (RED) drugs and clinical guidelines recently approved by CDDFT was presented to the group.

The APC noted the following RED drugs have been approved by CDDFT:

- Evotaz®
- Rezolsta®
- Idarucizumab
- Akynezo®

ACTION:

- **GM to update the formulary accordingly.**

3j Regional Medicines Optimisation Committee – update

ID presented an update to the group progress with the formation of the four Regional Medicines Optimisation Committees for England which will be established by the end of summer 2016. The APC will be kept informed of future developments/progress.

Part 4 – Physical Health (13.30)

4a Lidocaine Patch Guideline

Discussed under review of Matters Arising/Action Log.

4b County Durham & Darlington Diabetes Integrated Model – Prescribing Guidelines

Dr Ojechi and Dr Partha presented the final draft of the prescribing guidelines to support the new County Durham & Darlington Diabetes Integrated Model for approval. The APC approved the guideline subject to the following changes being made:

- GLP-1s – the most cost-effective option (e.g.lixisenatide) should be used first line rather than liraglutide in the absence of any other patient specific factors affecting product choice.
- The term DPP-4 inhibitors should be used throughout the document instead of Gliptin.
- Following diagnosis HbA1c should be measured every 3 months BUT drug therapy should not be initiated until 3 months after DESMOND or 6 months after initial diagnosis to give time for lifestyle measures to have an impact prior commencing drug therapy.
- High-strengths insulins should be used on specialist advice in the community.
- It should be made clear that insulin degludec is currently non-formulary.
- The line "Any long-standing prescriptions for generic 'glargine' should be changed to Lantus but for new initiations Abasaglar is recommended. (NB human insulin remains the first-line choice for most patients)" should be removed.

ACTION:

- **KH to make suggested changes to document and approve via Chair's Action**
- **GM to arrange for document to be added to CD&D pages of NECS website once approved via Chair's Action**
- **GM to update the formulary once the guideline is approved.**

4c Erectile Dysfunction Guidelines

The final draft of the local prescribing guidelines for erectile dysfunction incorporating the suggested changes from the March 2016 APC was approved.

ACTION:

- **GM to arrange for document to be added to CD&D pages of NECS website**

4d Regional Antibiotic Guideline

The updated Regional Antibiotic Guideline was presented to and approved by the group. Comments were made about the practicalities of the review date/process and these will be fed back to the authors.

ACTION:

- **DN to arrange for document to be added to CD&D pages of NECS website.**

4e Analgesia Formulary Choices

Recent audits of controlled drug prescribing within County Durham have highlighted increasing prescribing of oxycodone and tapentadol. The APC discussed what actions could be taken locally to address this use and ensure prescribing of these agents was appropriate. It was agreed to develop a guideline for the use of strong opioids locally.

ACTION:

- **GM to circulate examples of Strong Opioid Guidelines in other areas as a basis for producing a local guideline**

4f DVT Pathway – minor change

A minor change to the local DVT pathway around the use of compression stockings was presented to and approved by the group.

ACTION:

- **AR to arrange for updated DVT pathway to be added to CD&D pages of NECS website.**

4g INR Self-Testing

The APC noted that Roche are currently undertaking a local media campaign to promote INR self-testing to warfarin patients.

The APC noted that the North Durham, DDES and Darlington CCGs have already sent a memo to GP practices to remind GPs that within County Durham and Darlington the costs of the self-testing strips need to be met by the AQP INR monitoring provider, and that they should not be prescribed by GPs.

Part 5 – Standing items (for information only)

5a Formulary Steering Group Minutes February 2016
For information.

5b Formulary Amendments Post-April 2016 FSG Meeting
For information.

5c TEWV D&T Minutes January 2016
For information.

5d CD&D FT Clinical Standards and Therapeutics Committee April 2016 Minutes
For information.

5e CD&D D&T CAG February 2016 Minutes
For information.

5f Diabetes Prescribing Group Minutes
Not yet available.

5g NTAG Minutes November 2015
For information.

5h RDTC Horizon scanning – March & April 2016
For information.

5i MHRA Drug Safety Update – March & April 2016
For information.

Chairman's Action

High Cost Drugs Group Terms of Reference
Approved

Drug Monitoring Document
Approved following clarification of points raised at March 2016 APC meeting.

Any Other Business
Nil

Date and time of next meeting:
Thursday 7th July 2016 11.30am – 2.30pm
Board Room, Appleton House