County Durham and Darlington Area Prescribing Committee

Thursday 7th January 2016
11.30am – 2.30pm
Board Room, North Durham CCG, Rivergreen Centre, Aykley Heads, Durham

MINUTES

Present

Dr Ian Davidson, Director of Quality & Safety, North Durham CCG (chair)
Dr Catherine Harrison, GP Prescribing Lead, DDES CCG
Gavin Mankin, RDTC Representative (Professional Secretary)
Andy Reay, Senior 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
Jamie Harris, Deputy Chief Pharmacist, CD&DFT
Rob Pitt, LPC representative
Dr Alwyn Foden, Consultant, CD&DFT
Melanie Robinson, Non-medical Prescriber, DDES CCG
Dan Newsome, Medicines Optimisation Pharmacist, NECS

In attendance
Beverley Walton, Lead Clinical Pharmacist, CD&DFT

The meeting was not quorate for Part 1 – Mental Health but as not decisions required for this section of agenda it was agreed to continue with meeting.
The meeting was quorate from Part 2 onwards.

Part 1 – Mental Health (11.30)

1a TEWV Drug & Therapeutics Committee Feedback – December 2015

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:

- Smoke free plan – see agenda item 1b
- Primary Care Physical Health Guidelines - been agreed that TEWV would adopt physical healthcare prescribing guidelines from different localities.
- Drugs for Alcohol Dependence – County Durham – document now approved and will be added to the website.
- When to stop ant-dementia drugs – no changes to current guidance at this time.
- Vortioxetine – current antidepressant guideline will be amended and will come to March 2016 APC.
- Camcolit 250® brand name change - The name change for Camcolit 250mg tablets (to Lithium Carbonate Essential Pharma 250 mg film coated tablets) was discussed. It has been agreed that prospectively, Priadel® will the preferred brand. TEWV requested patient numbers from primary care to consider the scale of impact for this change and therefore whether further advice is needed.

ACTION:

- **TEWV requested patient numbers from primary care to consider the scale of impact for this change and therefore whether further advice is needed.**
- **To scope how many patients within in primary care are currently receiving lithium outside of existing shared care guideline and for identified patients to be reviewed.**

1b TEWV Smoke-free plan

TEWV will be going smoke-free from 9th March 2016 and a verbal update on this was presented to the APC.

1c Effects of Stopping Smoking in Mental Health Drugs

A document highlighting the effects of stopping smoking on mental health drugs was presented to the group.
It was approved by the group for circulation to GPs within County Durham & Darlington.

ACTION:

- **JS/KH/AR to send out Effects of Stopping Smoking in Mental Health Drugs document to primary care and include in primary care newsletter.**

1d TEWV Guidance on Safe Prescribing of Melatonin

The final approved document to ensure safe prescribing of melatonin within Tees, Esk and Wear Valleys NHS Foundation Trust and then to appropriately transfer prescribing to primary care was presented to the group for information.
It includes the licensed Circadin® product as the product of choice over the unlicensed formulations. This includes the crushing of Circadin® where required for the purposes of dose administration.
The APC noted CDDFT and currently CD&D shared care guideline prompt Circadin® as the product of choice, and not changes to existing CD&D shared care guideline for melatonin were required.

ACTION:

- **GK to discuss if CDDFT clinicians happy to adopt licensed Circadin® as product of choice and to crush as necessary, rather than using other unlicensed formulations.**
- **Primary Care workplan to include switching patients from melatonin specials to Circadin®.**

1e Psychotropic Prescribing: Peri-pregnancy and in Women of Child Bearing Age

A document produced by TEWV discussing the issues around psychotropic drug prescribing in the peri-pregnancy period and in women of child bearing age was presented to the group.
It was approved by the group for circulation to GPs within County Durham & Darlington with the suggested addition of lamotrigine.

ACTION:

- **JS/KH/AR to send out Psychotropic Prescribing: Peri-pregnancy and in Women of Child Bearing Age document to primary care and include in primary care newsletter.**
- **CW to arrange for document to be added to CD&D pages of NECS website.**

Part 2 – General (12.00)

2a Apologies for absence:
James Carlton, Martin Jones, Mike Leonard, Ingrid Whitton, Sarah McGeorge, Claire Jones, Jo Linton, Betty Hoy, Alex Murray

2b Declarations of Interest
No declarations of interest relating to the agenda were raised.

It was agreed that the APC declarations of interest register for 2014/15 could be added to the website.

Members were reminded it is their responsibility to keep declarations of interest up to date.

It was also agreed to highlight to APC members the manufacturer for any new formulary drug applications that are received.

ACTION:
- **GM to add APC declarations of interest register for 2014/15 to website.**
- **GK to review CDDFT membership vacancies on APC with Medical Directors Office.**

2c Minutes of the previous APC meeting held 5th November 2015
The minutes were accepted as a true and accurate record.

2d Matters arising/action log

Actions From November 2015 Meeting not on the agenda or action log
Nil

Action Log
TEWV Smoke-free Plan
Now approved by TEWV D&T. Document on effects of stopping smoking on mental health drugs on today's agenda. It was agreed that this item was now CLOSED.

Alcohol Drugs – Supporting Information
Documents were approved at TEWV D&T in December 2015.

SBARD in Relation to the Monitoring of Lithium Plasma Levels
Memo has now been circulated to primary care. It was agreed that this item was now CLOSED.

TEWV Guidance on Safe Prescribing of Melatonin
Document was approved at December 2015 TEWV D&T and on today's agenda for information.

Gender Dysphoria Regional Guidelines
Published on website and formulary has been updated. It was agreed that this item was now CLOSED.

Oxycodone Prescribing Safely
Memo has now been circulated to primary care. It was agreed that this item was now CLOSED.

Branded Prescribing of Combination Inhalers
Memo has now been circulated to primary care. It was agreed that this item was now CLOSED.

DMARD Shared Care Guidelines
On today's agenda.

CD&D Drug Monitoring Document
Published on website following Chairman's action but since then further changes needed have been identified. It was agreed that an updated version be produced and approved by Chairman's action by 15th January 2016. Until then the most up to date version will remain on the website.

ACTION:

- **DN to finalise drug monitoring document with chair by Friday 15th January 2016.**

Asthma Guideline
Published on website and formulary has been updated. It was agreed that this item was now CLOSED.

Osteoporosis Guideline
On today's agenda for verbal update.
Noted that NICE TA update of bisphosphonates has been delayed and currently has not revised date of publication.

High Cost Drugs Update
The first meeting of subgroup to take this workstream forward is scheduled for 7.1.2016. JS has been identified as the lead for this workstream and the group will meet monthly.

ACTION:

- **JS to bring Terms for Reference to High Cost Drugs Group to March 2016 APC.**

Food Supplement Contracting Issues
The issue has been referred to CCG Executive Committees for a decision who have asked to see a copy of the contract. It was agreed that this item was no longer in the remit of the APC to resolve but to keep it on the action log so it does not get lost.

Diabetes Board
Terms of Reference now agreed and first meeting to be in January 2016. It was agreed that this item was now CLOSED.

Historic Actions

Subcutaneous Methotrexate
Work ongoing. GK continues to explore options with current homecare provider and look into FP10 option.

Dressings Formulary Update
Supporting documents now complete and published on website plus formulary has been updated. It was agreed that this item was now CLOSED.

Neuropathic Pain Audit
Aiming for a lidocaine patch guideline to come to March 2016 APC.

Lipid Guidelines – Lifestyle advice
Published on website. It was agreed that this item was now CLOSED.

Letrozole and DEXA Scans
Regional Breast Site Specific Group discussed on 5.11.15 and the agreed the following course of action:

- CDD (and South Tees) are outliers across the region – other Trusts the scans are organised when the decision is made to initiate treatment.
- The Breast SSG agreed to undertake an audit to compare both processes as both feel that the other is more likely to result in missed scans or results not being actioned.

- If the outcome is that it is safer for scans to be organised in secondary care then we would propose that the Breast Cancer Nurse Specialist would order the scan, receive the results and then action by completing a Treatment Recommendation Form to ask the GP to initiate the appropriate treatment to save the patient attending an outpatient clinic.

GK will keep the APC informed of progress.

NICE NG5 – Medicines Optimisation
On today's agenda.

APC Formulary steering group update

2e Update from Formulary Subgroup for January 2016 APC
This was presented to the group and the following actions were taken by the APC:

Formulary Updates since November 2015 APC for approval including RAG changes
Approved with suggested changes to RAG recommendation as follows:

BNF Chapter	BNF Category Number	Product/indication	Detail of change	Date Guidance Issued	RAG Status
6	6.4.1.1	HRT	Add link to NICE NG23	25.11.15	No change. HRT listed as GREEN
6	6.4.1.2	Progesterone pessaries for preterm labour and buth	Include progesterone pessaries in formulary and add link to NICE NG25.	25.11.15	Add progesterone pessaries as RED drug for this indication
8	8.1.5	Pembrolizumab for treating advanced melanoma after disease progression with ipilimumab	Include in formulary and add link to NICE TA357.	28.10.15	Add as a RED drug as per all other chemo drugs
6	6.5.2.2	Tolvaptan for treating autosomal dominant polycystic kidney disease	Include link in the formulary and add as RED drug for this indication because only available by PAS scheme and requires specialist to initiate. Note this condition is not managed by CDDFT.	28.10.15	Add as RED drug. Need to ensure indication clear on formulary and wording matches that North of Tyne.
8	8.1.5	Idelalisib for treating chronic lymphocytic leukaemia	Include in formulary and add link to NICE TA359.	28.10.15	Add as a RED drug as per all other chemo drugs
8	8.1.5	Paclitaxel as albumin-bound	Include in	28.10.15	Add as a

		nanoparticles in combination with gemcitabine for previously untreated metastatic pancreatic cancer Paclitaxel as albumin‑bound nanoparticles in combination with gemcitabine is not recommended within its marketing authorisation for adults with previously untreated metastatic adenocarcinoma of the pancreas.	formulary and add link to NICE TA360.		REJECTED drug for this indication.
5	5.3.3.2	Simeprevir in combination with sofosbuvir for treating genotype 1 or 4 chronic hepatitis C (terminated appraisal)	Add link to NICE TA361.	28.10.15	No action required except to add link to formulary.
8	8.1.5	Paclitaxel as albumin-bound nanoparticles with carboplatin for untreated non-small-cell lung cancer (terminated appraisal)	Add link to NICE TA362.	28.10.15	No action required except to add link to formulary.
5	5.3.3.2	Ledipasvir–sofosbuvir for treating chronic hepatitis C	Include in formulary and add link to NICE TA363.	25.11.15	Add as a RED drug as per all other anti-retrovirals for Hep C.
5	5.3.3.2	Daclatasvir for treating chronic hepatitis C	Include in formulary and add link to NICE TA364.	25.11.15	Add as a RED drug as per all other anti-retrovirals for Hep C.
5	5.3.3.2	Ombitasvir–paritaprevir–ritonavir with or without dasabuvir for treating chronic hepatitis C	Include in formulary and add link to NICE TA365.	25.11.15	Add as a RED drug as per all other anti-retrovirals for Hep C.
8	8.1.5	Pembrolizumab for advanced melanoma not previously treated with ipilimumab	Include in formulary and add link to NICE TA366.	25.11.15	Add as RED drug as per all other chemo drugs.
4	4.3.4	Vortioxetine for treating major depressive episodes	Include in formulary and add link to NICE TA367. To ensure NICE guidance clear on the formulary	25.11.15	Add as 3rd line GREEN ALT drug as per updated TEWV guideline for the management of depression + NICE TA.
13	13.5.3	Apremilast for treating moderate to severe plaque psoriasis	Add link to NICE TA368	Not listed in section 13.5.3	Add as a REJECTED drug for this indication.
7	7.4.2	Mirabegron (Betmiga▼): risk of severe hypertension and	Add link to MHRA DSU	Oct 2015	No change

		associated cerebrovascular and cardiac events	guidance. Also suggested should be included in drug monitoring document.		
8	8.1.5	Crizotinib (Xalkori▼): risk of cardiac failure	Add link to MHRA DSU guidance	Nov 2015	No change
8	8.1.5	Vemurafenib (Zelboraf▼): risk of potentiation of radiation toxicity	No action required as not included in formulary	Nov 2015	No change
2	2.7.2	Midodrine – licensed product now available	Change RAG status from RED as licensed product now available.	n/a	Change to Green+

The APC also noted that CDDFT currently have a number of patients receiving apremilast free of charge provided by the manufacturer. The feeling of the APC was that no new patients should initiated on apremilast as the drug was not approved for use by NICE.

ACTION: GM to update the online formulary with the approved changes.

2f New Drug Applications

Dulaglutide

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

It was agreed that should be classed as GREEN PLUS drug as per all the other GLP-1s and should be the 1st choice weekly GLP-1 preparation.

The APC noted that the Diabetes CAG are currently reviewing all the 1st line, 2nd line formulary choices for each of the different classes of antidiabetic drugs.

ACTION: GM to update the online formulary with the approved change.

2g DMARD Shared Care Guidelines

Noted that existing DMARD shared care guidelines are currently being reviewed and updated, including incorporating all specialities/indications for DMARDs.

The updated Methotrexate SCG and Hydroxychloroquine SCG were presented to the APC for approval.

Methotrexate SCG

This was approved by the APC with the following changes and a review date of 2 years:

- Add need to prescribe as 2.5mg tablets.
- Update wording on GP responsibilities to match that in existing SCG.
- Add requirements for monitoring for respiratory indications.
- Clarify and specify what is the normal range for WBC and neutrophils.
- Renal impairment – clarify wording re 50% change from baseline and in what

timeframe.

Hydroxychloroquine SCG

This was not approved by the APC as the reason for the difference in monitoring requirements between rheumatology and dermatology patients was not clear. Also concerns were expressed that GPs would not accept the proposed monitoring requirements for dermatology patients

ACTION:

- **JH to establish national and regional position on monitoring of hydroxychloroquine in dermatology for further discussion at March 2016 APC.**
- **JH to update Methotrexate SCG with suggested changes prior to publication on website.**

2h NTAG Update:

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

- Alirocumab for the treatment of primary hypercholesterolaemia and mixed dyslipidaemia - The Northern (NHS) Treatment Advisory Group does not recommend the use of alirocumab for the above indication. The group noted that whilst phase III trials involving 5296 patients demonstrated a substantial reduction in the primary end point of LDL-C reduction after 24 weeks, there is currently insufficient data on the effect of alirocumab on CV morbidity and mortality and therefore questions remain around the level of risk reduction and therefore the cost effectiveness of treatment. The group also considered the use of alirocumab for a specific subgroup of patients who would otherwise be eligible for apheresis, as advised by specialists however there is insufficient information on efficacy of alirocumab in this patient population. The group was concerned about the level of clinical benefit (i.e risk reduction) versus the high cost of alirocumab in this patient group. It was noted that the current cohort of patients were not receiving apheresis and reasons for this should be explored first. Alirocumab may be suitable for those patients with heterozygous familial hypercholesterolemia (HeFH) who are at very high risk however it was felt that these patients should be managed on a case by case basis. The group is aware that a NICE technology appraisal review is currently underway and agreed that NICE is best place to assess cost effectiveness due to the current gaps in the data and will await this guidance.
- Evolocumab for the treatment of primary hypercholesterolaemia and mixed dyslipidaemia - The Northern (NHS) Treatment Advisory Group does not recommend the use of evolocumab for the above indication. The evidence for the clinical efficacy and safety of evolocumab is limited, with the majority of the evidence for efficacy derived from five phase III trials, each lasting 12 weeks. Only one phase III trial lasted 52 weeks. There is currently insufficient data on the effect of evolocumab on CV morbidity and mortality and therefore questions remain around risk reduction, cost effectiveness and affordability of treatment.
  The group also considered the use of evolocumab for a specific subgroup of patients who would otherwise be eligible for apheresis, as advised by specialists however there is insufficient information on efficacy of evolocumab in this patient population. The group was concerned about the level of clinical benefit versus cost of evolocumab in this patient group. It was noted that the current cohort of patients were not receiving apheresis and reasons for this should be explored first. Evolocumab may be suitable for those patients with heterozygous familial hypercholesterolemia (HeFH) who are at very high risk however it was felt that these patients should be managed on a case by case basis. The group is aware that a NICE technology appraisal review is currently underway and agreed that NICE is best place to assess cost effectiveness due to the current gaps in the data and will await this guidance.
- Insulin glargine biosimilar (Abasaglar®) – The Northern (NHS) Treatment Advisory Group recommends the use of Abasaglar© insulin glargine biosimilar as a first line option for use in adults who are eligible for treatment with insulin glargine as per NICE guidance (NG17, 2015)
- Insulin glargine high strength (Toujeo®) - The Northern (NHS) Treatment Advisory Group recommends the use of Toujeo® insulin glargine as an option for use in adults who are eligible for treatment with insulin glargine as per NICE guidance (NG17, 2015).
  The group noted that Toujeo® was shown to be non-inferior to Lantus® in reducing HBA1c in both T1DM and T2DM. Toujeo® represents an additional treatment option for patients that require a long-acting insulin analogue and who are not currently able to achieve optimal glycaemic control. Due to a flatter and more prolonged pharmacodynamic profile Toujeo

allows patients greater flexibility in the timing of their once-daily injection compared with Lantus and offers the advantage of a smaller volume of injection.
However, switching from Lantus to Toujeo is not straightforward, as the drugs are not bioequivalent and are not directly interchangeable. A switch can be done on a unit-to-unit basis, but higher doses of Toujeo (approximately 10-18%) may be required to achieve similar levels of glucose control.
If used Toujeo® must be prescribed by brand name to prevent any confusion.
It should be noted that the Solostar® pen will only discharge a maximum of 80 units in one injection.

The formulary website will be updated accordingly.

2i Accelerated Access Review: Interim Report

The national Accelerated Access Review: Interim Report around improving access to innovative medicines across the country was presented to the group for information.

2j Prescribing Outlook 2015

Regional cost impact calculator has now been produced by RDTC and NECS. This has been circulated to CCGs. Noted that savings from new generics in 2016/17 are limited and that the impact of licensed medicinal versions of e-cigarettes is an area of possible high financial risk and unknowns.

2k NHSE Specialised Commissioning Drugs Briefing; Dec 2015

The December 2015 Specialised Commissioning Drugs Briefing was presented to the group for information. This Briefing brings together in one place updates on medicines commissioned by NHS England and is produced on a quarterly basis by NHS England.

2l NICE NG5 – Medicines Optimisation – Key Priorities for Implementation

Locally identified risks/gaps across the interface from each of the APC stakeholders were presented for discussion. It was noted that is still work in progress.
The following points were raised/agreed during discussion:

- Cross boundary issues are area for discussion by the APC.
- CCG Quality Review Group need to see these baseline assessments.
- A need for a subgroup of APC to take this workstream forward was identified.
- Every guideline that comes to APC for approval should state on cover sheet if there is a patient decision aid available.
- Some suggested key priorities locally were:
    - Transfer of patients across care boundaries
    - Need some examples of best practice
    - Patient Decision Aids

ACTION:

- **Subgroup to be formed to take this NICE NG5 workstream forward with regard to the issues that need to be considered by the APC e.g. interface issues.**
- **ID to take NICE NG5 – Medicines Optimisation baseline assessment to local CCG Quality Review Groups for action planning.**

Part 3 – Physical Health (13.00)

3a Water for Home Ventilation – NHSE Letter

Correspondence received from NHS England with regard to the prescribing of water for home ventilation in primary care was circulated to the group for information. It was noted that this had also been circulated to primary care.

3b Use of Patient Decision Aids to Discuss Anticoagulant Choice

Concerns were expressed that full discussion on anticoagulant choice with

patient (as per NICE TAs for NOACs) is not currently taking place in secondary care, or if it is that such discussions are not being documented then subsequently communicated to the GP.

ACTION:

- **To refer issue to suggested sub-group on Medicines Optimisation.**

3c **Osteoporosis Guideline**

Work has begun on developing a local osteoporosis guideline with the involvement of clinicians from secondary care. It was noted that a NICE TA on Bisphosphonates for preventing osteoporotic fragility fractures has now been delayed indefinitely. It was agreed that local guidance was still needed especially around stopping bisphosphonates and bisphosphonate "holidays".

ACTION:

- **Dan Newsome (NECS) to work with secondary care to produce a local osteoporosis guideline.**

Part 4 – Standing items (for information only)

4a **Formulary Steering Group Minutes October 2015**
For information.

4b **Formulary Amendments Post-December 2015 FSG Meeting**
For information.

4c **TEWV D&T Minutes September 2015**
For information.

4d **CD&D FT Clinical Standards and Therapeutics Committee August 2015 Minutes**
For information.

4e **CD&D D&T CAG October 2015 Minutes**
For information.

4f **NTAG Minutes September 2015**
For information.

4g **RDTC Horizon scanning – November & December 2015**
For information.

4h **MHRA Drug Safety Update – November & December 2015**
For information.

Chairman's Action

Asthma Guideline

Minor changes to formatting suggested by Respiratory CAG following approval of guideline at November 2015 APC were approved.

Drug Monitoring Document

See discussion under Matters Arising/Action Log.

Any Other Business

Psoriasis Pathway

This was presented to the group for approval. It was noted that had previously been approved by CDDFT CTSC in December 2014. The APC was not clear if this guideline was only intended for use in secondary care and felt the layout could be improved.

ACTION:

- **JH to invite appropriate clinicians to March 2016 APC to present and discuss guideline.**

Blood Glucose Testing Strips

The current local guideline is due for review in March 2016. It was agreed to extend this review date to September 2016 because the choice of strips is be reviewed regionally.

Date and time of next meeting:

Thursday 3rd March 2016 11.30am – 2.30pm

Meeting Room 3, Education Centre, Lanchester Road Hospital