Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay Clinical Commissioning Group

Clinical Policy Committee (CPC)
Minutes

Wednesday 24th February 2016, 9.30 am to 12.30 pm

Committee Suite, County Hall, Exeter

Present:

Dr Andrew Craig (Chair)*	GP Clinical Commissioner	NEW Devon CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Jono Broad	Lay Member	
Richard Croker	Head of Medicines Optimisation Northern and Eastern Localities	NEW Devon CCG
Paul Foster	Chief Pharmacist	T&SD NHS FT
Dr Andrew Gunatilleke	Consultant in Pain Management and Anaesthesia	T&SD NHS FT
Barbara Jones	Head of Locality Contracting	NEW Devon CCG
Dr Mark Kealy	Consultant in Public Health	Devon County Council
Andrew Kingsley**	Patient Safety and Quality	NEW Devon CCG
Dr Peter Leman*	GP Clinical Commissioner	NEW Devon CCG
Dr Phil Melluish*	GP Clinical Commissioner	South Devon and Torbay CCG
Mac Merrett	Lay Member	
Michael Rodgers	Management Accountant, Finance	NEW Devon CCG
Chris Roome*	Head of Clinical Effectiveness	NEW Devon CCG
Dr Alison Round*	GP Clinical Commissioner	NEW Devon CCG
Dr Darunee Whiting*	GP Clinical Commissioner	NEW Devon CCG

Guests:

Mr Mark Cartmell	Colorectal Surgeon	NDHC NHS Trust
Kathryn Copping	Commissioning Support Officer - Planned Care	South Devon and Torbay CCG
Sean Costelloe	Consultant Clinical Scientist	Plymouth Hospitals Trust
Dr Eileen Deakin	Clinical Lead for Long Term Conditions	South Devon and Torbay CCG
Dr Alex Degan	Planned Care Lead GP	NEW Devon CCG
Dr Jim Forrer	Clinical Lead for Cancer	NEW Devon CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Steffan James	GR Registrar – Laboratory Representative	NDHC NHS Trust
Mr Martin Moody	Consultant Urologist	NDHC NHS Trust
John O'Connor	Consultant Clinical Scientist	RD&E FT
Dr Ed Parry-Jones	Clinical Lead for Long Term Conditions	NEW Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Mike Waterson	Consultant Biochemist	Torbay & South Devon NHS FT

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG

* Denotes voting members
** Denotes joined meeting by teleconference

1. Welcome and announcements

Apologies

Tawfique Daneshmend	Secondary Care Clinician	RDE& NHS FT
Miles Earl	Contract Accountant	NEW Devon CCG
Samantha Morton	Head of Contracting and Procurement	South Devon & Torbay CCG
Dr Jo Roberts	Clinical Member and Committee Chair	NEW Devon CCG
Dr Ben Waterfall	GP Clinical Commissioner	NEW Devon CCG

Dr Ben Waterfall had deputised voting to Chris Roome

Michael Rodgers attended the meeting as deputy for Miles Earl.

Notification of Any Other Business

Members were asked if they had any items of AOB to discuss.

Confirmation of voting members and Declarations of Interest

The seven voting members present were identified.

Declarations of Interest were collected. The chair reviewed the Declarations of Interest. It was noted that Dr Alison Round had declared that her spouse was the clinical lead for NICE guidance on suspected cancer. All Declarations of Interest are reported in the minutes.

Jono Broad reported that he had been appointed as a non-executive director for Northern Devon Healthcare Trust.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Faecal occult blood testing for patients with clinical features associated with an increased risk of cancer	Manufacturers of guaiac-based faecal occult blood tests and faecal immunochemical tests
Tadalafil 5mg tablets for lower urinary tract symptoms (LUTS) in adult men (Cialis®)	**Eli Lilly**
Alternative treatments:	
Any alternative oral medicine licensed for the treatment of benign prostatic hyperplasia (BPH), e.g. alpha blockers, 5-alpha reductase inhibitors, anticholinergics, diuretics or desmopressin	**various manufacturers**
Surgery for the treatment of benign prostatic hyperplasia (BPH)	As a provider of private treatments for patients with benign prostatic hyperplasia (BPH)

NAME OF ATTENDEE	ROLE	
Richard Croker	Head of Medicines Optimisation	Paid member of advisory boards for Galen Pharmaceuticals Ltd, Martindale Pharma, Galderma (UK) Ltd, ProStraken Group PLC, Menarini Farmaceutica Internazionale SRL and Sterling Anglian. Spouse practice pharmacist at Bideford Medical Centre (post part funded by CCG).
Dr Alex Degan		Brother is employed by Eli Lilly as Regional Digital Manager Has shares in various pharmaceutical companies through tracker funds. Spouse has shares in Astra Zeneca and also has shares in various pharmaceutical companies.
Matt Howard	Clinical Evidence Manager	In previous post attended a number of CPD events where refreshments may have been sponsored by a variety of pharmaceutical companies
Mac Merrett	Lay member	Chair of the Exeter Cancer User Group and Deputy Chair of the Peninsula Cancer Group.
Mr Martin Moody	Consultant Urologist	*Hospitality/sponsorship* Sponsored breakfast at cMDT meeting. Ate less than £5. Exact date not known but in last 12 months. Similarly at breakfast meeting for competitors. Again ate less than £5. Exact date not known.
Dr Alison Round	GP Clinical Commissioner	*Any family or business interests (including personal or family medical conditions) which could be seen as influencing views of the drug(s)/intervention under consideration.* Spouse is Clinical Lead for the NICE guidance on suspected cancer.

2. Minutes of the meeting held on 2nd December 2015 and matters/actions arising

A minor wording change to action 15/39 to remove the word 'policy' from the 'management of none routinely commissioned drugs' was noted.

Subject to this amendment, the minutes of the meeting held on 2nd December 2015 were approved.

Summary of actions		
	Action	**Lead**
15/30	*Policy recommendation and QEIA for fluticasone furoate and vilanterol trifenatate (Relvar® Ellipta®) combination inhaler for asthma to be prepared and subsequently progressed to final CCG approval and communication.* *The recommendation has been approved by the CCGs' Executive Groups. The policy will be published following discussion at the forthcoming FIGs.* The policy has been published. Action complete.	
15/31	*Policy recommendation and QEIA for Fluticasone furoate and vilanterol trifenatate (Relvar® Ellipta®) combination inhaler for chronic obstructive pulmonary disease to be prepared and subsequently progressed to final CCG approval and communication.* *The recommendation has been approved by the CCGs' Executive Groups. The policy will be published following discussion at the forthcoming FIGs.* The policy has been published. Action complete.	
15/32	*Policy recommendation and QEIA for the assessment and removal of benign skin and subcutaneous lesions to be prepared and subsequently progressed to final CCG approval and communication.* *The recommendation has been approved by the CCGs' Executive Groups and accompanying support information prepared. This will be published once an implementation date has been agreed by DRSS and Planned Care.* The policy has been published. Action complete.	
15/34	*Policy recommendation and QEIA for the routine commissioning of Budesonide prolonged release tablets (Cortiment®) for ulcerative colitis to be prepared and subsequently progressed to final CCG approval and communication.* The policy has been published. Action complete.	
15/35	*Policy recommendation and QEIA for the routine commissioning of Clindamycin 1%/Tretinoin 0.025% w/w gel (Treclin®) for the topical treatment of acne vulgaris to be prepared and subsequently progressed to final CCG approval and communication.* Publication pending. Item due to be discussed at the South and West Formulary Interface Group meeting on 9th March 2016.	Rebecca Heayn
15/36	*Policy recommendation and QEIA for the routine commissioning of Alogliptin (Vipidia®) for type 2 diabetes mellitus to be prepared and subsequently progressed to final CCG approval and communication.* The policy has been published. Action complete.	

15/37	*Policy revision recommendation and QEIA for assisted conception to be prepared and subsequently progressed to final CCG approval and communication.* Approval of QEIA awaited.	 Rebecca Heayn
15/38	*Meeting to be set up with clinicians regarding access criteria for treatment with BoNT A for the management of blepharospasm and for the management of hemifacial spasm*. In progress, an update will be provided at the next meeting. Item to be included on next meeting agenda.	 Matt Howard Rebecca Heayn
15/39	*Agreed minor amendments to be incorporated into the paperwork for the management of non-routinely commissioned drug treatments. Communication to primary and secondary care to be planned.* This had been raised at the Eastern locality Board meeting; it was suggested that a list of drugs is maintained.	 Petrina Trueman
15/40	Aspects of feedback to CPC following meetings of the Clinical Policy Engagement and Consultation Panel meeting to be agreed. On agenda. Action complete	

3. Faecal occult blood testing for patients with clinical features associated with an increased risk of colorectal cancer

NICE issued an updated clinical guideline for referral for suspected cancer (NG12) in June 2015. This guideline included a new recommendation under referral for suspected colorectal cancer for faecal occult blood testing by primary care for selected groups of patients. Referral for an appointment within two weeks is recommended for patients with a positive faecal occult blood test. This recommendation represents a change in practice because faecal occult blood tests are not currently available to primary care. The recommendation also includes new patient groups who were not considered under previous NICE guidance for referral for suspected cancer (CG27). Hilary Pearce, Clinical Effectiveness Pharmacist, NEW Devon CCG presented an evidence review. Mr Mark Cartmell, Colorectal Surgeon, NDHC NHS Trust, Sean Costelloe, Consultant Clinical Scientist, PHT, Dr Eileen Deakin, Clinical Lead for Long Term Conditions, South Devon and Torbay CCG, Dr Alex Degan, Planned Care Lead GP, NEW Devon CCG, Dr Jim Forrer, Clinical Lead for Cancer, NEW Devon CCG, Steffan James, GP Registrar – Laboratory Representative, NDHC NHS Trust, John O'Connor, Consultant Clinical Scientist, RD&E NHS FT and Mike Waterson, Consultant Biochemist, Torbay & South Devon NHS FT joined the meeting for the discussion of this item.

The NICE Guideline Development Group agreed that the potential benefit of faecal occult blood testing will be to filter out those patients with symptoms who are less likely to have colorectal cancer and do not warrant a suspected cancer pathway referral. Testing will also expedite the diagnosis of people who do have colorectal cancer. There are two types of faecal occult blood test, the guaiac-based test and the faecal immunochemical test (FIT). Evidence for both tests was considered by NICE. The evidence review presented to the Clinical Policy Committee included the clinical and cost effectiveness evidence presented by NICE in support of the recommendation for faecal occult blood testing, the NICE Guideline Development Group rationale for the patient groups selected for testing and the position of other national organisations on faecal occult blood testing. The Clinical Effectiveness team undertook literature searches to update the NICE clinical effectiveness review and to determine whether there were comparative studies for the two tests in primary care patients. It was noted that NICE has not estimated the cost of implementing the new recommendation for faecal occult blood testing nor

have they estimated the impact of this recommendation on two week wait pathways and capacity for investigative procedures.

The committee considered a number of issues pertinent to this recommendation:

- If faecal occult blood testing is commissioned in primary care should the guaiac test or FIT test be used? NICE is planning to issue a diagnostic technology appraisal for FIT to triage low risk populations for suspected colorectal cancer referrals in 2017. It may be more sensible to wait for this guidance rather than set up to use the guaiac test sooner and changing to FIT at a later date.
- It is better for patients to be diagnosed early, survival times are markedly increased for diagnosis at early stage rather than late stage colorectal cancer. The lifetime healthcare costs are also lower for early stage diagnosis. However, it was noted by the specialist present that many patients who are diagnosed with colorectal cancer following an emergency presentation have not consulted their GP prior to admission and this limits the opportunity to identify patients at an earlier stage of cancer unless a means can be found to encourage these patients to come forward earlier.
- Impact on services: the number of patients who fall into the patient groups recommended for testing by NICE was estimated using publications referenced by NICE. However, the proportion of these patients currently referred for colonoscopy is not known. It was generally considered that the new guidance would result in an increase in referrals. A large number of colorectal cancer cases are currently diagnosed with late stage cancer and require emergency surgery. Given that faecal occult blood testing is expected to result in an increase in referrals for colonoscopy, the introduction of testing would be expected to have a considerable impact on the overall service unless there is a corresponding decrease in emergency presentations thus freeing up clinical time currently taken up by these cases.
- It was noted that the key point in relation to use of quantitative FIT tests was that the faecal haemoglobin cut-off for a positive test has not been agreed for symptomatic patients. A low cut-off increases sensitivity for colorectal cancer but has a lower specificity resulting in more referrals for investigation. Some of the studies included in the discussion paper highlighted the impact of testing on resources and the large number of positive tests at low cut-off values for FIT.
- NICE recommend ‘safety-netting’ patients with clinical features associated with an increased risk of cancer and a negative faecal occult blood test. These patients have often had symptoms for some time and these symptoms will continue. It was suggested that patients with colorectal cancer not detected by faecal occult blood testing may not be picked up until a much later stage.

The committee voted unanimously that faecal occult blood testing in the groups defined by NICE for suspected colorectal cancer should be recommended in the local health community. Implementation needs further work and will be guided by the evidence and the laboratories work up in consultation with the consultants who carry out colonoscopies. The general consensus seemed to favour FIT with patient advantages and imminent adoption by the screening programme. Implementation of this new test will require proceeding with caution. To the knowledge of the clinical effectiveness team other areas are yet to decide on this issue and the SW Cancer Network is interested in how Devon is progressing. The Clinical Effectiveness team intend to liaise with the SW Cancer Network Manager regarding next steps. This is likely to involve some local pilot work to inform a final decision on implementation with data on costs and service impacts.

ACTION: Clinical Effectiveness Team to contact SW Cancer Network Manager to explore options for next steps.

4. Tadalafil (Cialis®) 5mg tablets for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult males

A formulary application has been received from a Consultant Urologist at RDE requesting the inclusion of tadalafil 5mg tablets for the treatment of lower urinary tract symptoms (LUTS) resulting from benign prostatic hyperplasia (BPH) in adult men. Matt Howard, Clinical Evidence Manager, NEW Devon CCG presented an evidence review. Mr Martin Moody, Consultant Urologist, Northern Devon Healthcare Trust joined the meeting and took part in the discussion of this item.

Tadalafil is a reversible phosphodiesterase-5 inhibitor (PDE5I); originally licensed for the treatment of erectile dysfunction (ED) in adult males it is also licensed to treat the signs and symptoms of BPH in adult males. Tadalafil 5mg tablets once daily would be a possible treatment for men not responding to alpha-blockers, experiencing adverse effects of alpha-blockers and as first line option for men with comorbid LUTS and ED. The applicant indicated that use of tadalafil 5mg tablets in this cohort might avoid surgery such as transurethral resection of the prostate (TURP). LUTS include voiding and storage symptoms. Although LUTS do not usually cause severe illness quality of life can be considerably reduced; bothersome LUTS occur in up to 30% of men over 65 years.

In 2005 NICE published an update to clinical guideline CG97: Lower urinary tract symptoms in men: management. A number of conservative management options were recommended and the guidance states that drug treatment should only be offered to men with bothersome LUTS when conservative management options have been unsuccessful or are not appropriate. NICE recommended drug treatment options include alpha blockers, anticholinergics, and 5-alpha reductase inhibitors. The guidance states “Do not offer phosphodiesterase-5-inhibitors solely for the purpose of treating LUTS in men, except as part of a randomised controlled trial.” The Scottish Medicines Consortium and the All Wales Medicines Strategy Group do not recommend tadalafil for treatment of the signs and symptoms of BPH for use in NHS Scotland or NHS Wales respectively.

The committee reviewed the clinical evidence. Clinical trial data from a number of RCTs have been published and subject to multiple meta-analyses by NICE and others. NICE found no clinically important difference between tadalafil and placebo for change from baseline in International Prostate Symptom Score (IPSS). For quality of life, NICE found no clinically important difference between tadalafil and placebo for change from baseline in IPSS Quality of Life (QoL). NICE also concluded that there was no difference in the effects of tadalafil vs alpha-blocker but noted that the evidence was not sufficiently powered or analysed as a non-inferiority or equivalence trial and therefore cannot be interpreted as showing that PDE5I are as effective as alpha blockers. Two additional meta-analyses of smaller datasets which reported tadalafil specific data found similar results. In these analyses, results for a subgroup of patients with comorbid LUTS and ED were numerically lower than those seen in a mixed population. Two further meta-analyses reporting data relating to PDE5I generally, rather than tadalafil specifically, again did not find a clinically important difference between PDE5I and placebo for change from baseline in total IPSS.

Treatment of LUTS with tadalafil 5mg tablets once daily rather than alpha blocker represents an additional annual expenditure of between £546 and £700 per patient. In the treatment of comorbid LUTS and ED combination treatment of alpha blocker plus “when required” PDE5I is generally less expensive than tadalafil 5mg tablets once daily monotherapy. Local specialist opinion varies with respect to predicted patient numbers and whether surgery might be avoided Estimates based on specialist opinion suggest an overall increase in expenditure across Devon in the region of £265,000 to £335,000 associated with the use of tadalafil 5mg tablets once daily for LUTS. NICE (2015) did not identify any economic evaluations comparing PDE5I to placebo or other medications for LUTS. The NICE committee concluded that PDE5I are unlikely to be cost effective. No subsequent economic evaluations were identified and the absence of suitable data precluded any trial health economic assessment.

Following circulation of the near final draft evidence appraisal paper to specialists involved in the consultation, the original application was withdrawn. Subsequently a Consultant Urologist at Torbay and South Devon NHS Foundation trust submitted an additional “article in press”

which was not available at the time of the CEMO literature search. The paper is a narrative review of prior review papers, and a summary of post hoc pooled subgroup analyses of data that discusses a number of publications already addressed in the CPC evidence appraisal paper and presents some additional reviews which had been considered and excluded. However, it is noted that the data presented in this additional paper do not appear to support the position that tadalafil 5mg once daily achieves an improvement of clinically meaningful urinary symptoms compared with placebo. Following submission of the additional paper a brief summary appraisal of it was sent to the Consultant Urologist at Torbay and South Devon NHS Foundation Trust asking if there was any pertinent information contained in the paper which he believes had not been addressed in the CPC evidence appraisal. At the time of the meeting no response had been received.

Following circulation of the final draft of the evidence appraisal paper an additional comment was received from a consultant urologist at Plymouth Hospitals NHS Trust who stated that:

He '*would be keen to continue using Cialis in the very small number of patients who are seeking management of both their ED and LUTS, not all patients admit to both problems and wish treatment. I would be happy to restrict its use to initiated by secondary care only'*.

The committee discussed a number of issues pertinent to this recommendation:

- Clinical evidence shows modest improvements in symptom scores of questionable clinical relevance.
- Tadalafil 5mg tablets once daily provide a more expensive option than most alternative treatment or combinations.
- It had been suggested that Tadalafil 5mg tablets once daily may prevent the need for TURP but specialist clinician views vary and there was no evidence of TURP avoidance.
- There may be small number of patients for whom the doctor considers tadalafil is required. In such circumstances application to the individual funding panel would be required.
- This drug was not considered appropriate for trust managed individual panel requests.

The committee voted unanimously against recommending the routine commissioning of Tadalafil 5 mg tablets for the treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.

ACTION: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.

5. Update from NICE Planning, Quality and Assurance Group (NPAG)

A verbal update from the NPAG meeting held on 10 November had been provided at the CPC meeting on 2nd December 2015.

The committee received a summary of the NPAG meeting which had taken place on 12 January 2016. The minutes and a summary of both NPAG minutes had been included with the meeting papers.

The NPAG meeting of 12 January 2016 had received ten NICE Technology Appraisals. These will be added to the local formularies within 90 days of publication.

In addition one social care guideline, two clinical guidelines, two pieces of medical technologies guidance, one piece of diagnostic guidance and six pieces of interventional procedures guidance had also been considered.

6. Update from Clinical Policy Engagement and Consultation Panel

The committee received the minutes of the Clinical Policy Engagement and Consultation Panel meetings which took place on 19th August 2015, 28th October 2015 and 6th January 2016.

It was reported that the Clinical Policy Engagement and Consultation Panel had not raised any concerns with regard to the public interest in any of the decisions taken by the Clinical Policy Committee.

It was reported that following discussion at the Clinical Policy Engagement and Consultation Panel supplementary patient information had been developed to support the publication of a number of policies.

7. Any Other Business

Date of next meeting

Junior doctors' strike dates have been announced which could affect the availability of specialists and committee members to attend CPC meetings. It was agreed that the CPC meeting scheduled to take place on Wednesday 9th March would be cancelled.

Subsequent to the meeting, it was agreed that due to the potential for junior doctors to be on strike on both 9th March and 27th April these meetings would be cancelled. A meeting is now scheduled to take place on Wednesday 20th April 2016.

Summary of actions

	Action	**Lead**
15/35	*Policy recommendation and QEIA for the routine commissioning of Clindamycin 1%/Tretinoin 0.025% w/w gel (Treclin®) for the topical treatment of acne vulgaris to be prepared and subsequently progressed to final CCG approval and communication.* Publication pending. Item due to be discussed at the South and West Formulary Interface Group meeting on 9th March 2016.	Rebecca Heayn
15/37	*Policy revision recommendation and QEIA for assisted conception to be prepared and subsequently progressed to final CCG approval and communication.* Approval of QEIA awaited.	Rebecca Heayn
15/38	*Meeting to be set up with clinicians regarding access criteria for treatment with BoNT A for the management of blepharospasm and for the management of hemifacial spasm*. In progress, an update will be provided at the next meeting. Item to be included on next meeting agenda.	Matt Howard Rebecca Heayn
15/39	Agreed minor amendments to be incorporated into the paperwork for the management of non-routinely commissioned drug treatments. Communication to primary and secondary care to be planned. This had been raised at the Eastern locality Board meeting; it was suggested that a list of drugs is maintained.	Petrina Trueman

16/01	Clinical Effectiveness Team to contact SW Cancer Network to explore options for next steps for Faecal occult blood testing for patients with clinical features associated with an increased risk of colorectal cancer.	Hilary Pearce
16/02	Policy recommendation and QEIA for Tadalafil (Cialis®) 5mg tablets for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult males to be prepared and subsequently processed to final CCG approval and communication	Rebecca Heayn