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

Clinical Policy Committee (CPC)
Minutes

Wednesday 4th June 2014, 14.00-16.00

Henlake Suite, The Watermark, Ivybridge PL21 0SZ

Present:

Dr Jo Roberts* (Chair)	GP Clinical Commissioner	South Devon & Torbay CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Jono Broad	Lay Member	
Julia Chisnell	Public Health Registrar	Devon County Council
Rob Cowdry	Contracts Governance Manager	NEW Devon CCG
Dr Andrew Craig*	GP Clinical Commissioner	NEW Devon CCG
Richard Croker	Head of Medicines Optimisation	NEW Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Dr Keith Gillespie*	GP Clinical Commissioner	NEW Devon CCG
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	SDHC NHS Foundation Trust
Andrew Kingsley	Patient Safety and Quality	NEW Devon CCG
Dr Phil Melluish*	GP Clinical Commissioner	South Devon & Torbay CCG
Mac Merrett	Lay Member	
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG
Dr Darunee Whiting*	GP Clinical Commissioner	NEW Devon CCG

Guests:

Gareth Franklin	Clinical Guidance Manager	NEW Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG

Observers:

John Bronze	Commissioner	NEW Devon CCG
Bethan Rogers	Clinical Evidence Pharmacist	NEW Devon CCG

In attendance:

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

* Denotes voting members

1. Welcome and introductions

Attendees were welcomed to the meeting and introduced themselves.
The Chair welcomed Jono Board, new lay member to the group.

Julia Chisnell attended the meeting as representative for Public Health.
Rob Cowdry attended the meeting as representative for Contracting and Business Intelligence.
Tawfique Daneshmend left the meeting at 11.30 am.

Apologies

Dr Stephen Hunt*	GP Clinical Commissioner	NEW Devon CCG
Paul Foster	Secondary Care Pharmacist	SDHC NHS FT
Tracey Foss	Secondary Care Pharmacist	RDE NHS FT
Simon Mynes	Secondary Care Pharmacist	PHT NHS FT
Niall Ferguson	Secondary Care Pharmacist	NDHC NHS Trust

Subsequent to the meeting apologies were also received from:

Dr Alison Round*	GP Clinical Commissioner	NEW Devon CCG

Confirmation of voting members and Declarations of Interest

The six voting members present were noted.

Declaration of interest forms were collected. The Chair informed the committee of declarations of interest received.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Lisdexamfetamine (Elvanse®)	**Shire**
Alternative treatments:	
Atomoxetine (Strattera®)	**Lilly**
Dexamfetamine	**various manufacturers**

NAME OF ATTENDEE	ROLE	
Dr Jo Roberts	Commissioner	Board Member of the Academic Health Sciences Network (AHSN). Recent presentation to Industry Engagement Event. Sits on Phama Industry Sector Board

Notification of Any Other Business

The chair asked the committee if there were any items to be discussed under Any Other Business. An update on an action relating to Exogen Ultrasound Bone Healing was identified.

2. Minutes of meeting held on 5th March 2014 and matters/actions arising

The minutes of the meeting held on 5th March 2014 were approved.

Actions from the previous meeting:

13/44 Details of identified South Devon and Torbay CCG appeals panel members to be provided

Action complete

14/01 Certolizumab pegol for the treatment of psoriatic arthritis commissioning policy to be published

Action complete

14/02 Certolizumab pegol for the treatment of ankylosing spondylitis commissioning policy to be published

Action complete

14/03 Bevacizumab for pathological myopia commissioning policy to be rescinded

Action complete

3. Lisdexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and adolescents

An application has been received requesting the inclusion of lisdexamfetamine into local formularies as an alternative second line treatment option for attention deficit hyperactivity disorder (ADHD) in children 6 years of age and over. The committee were asked to consider the evidence. Hilary Pearce, Clinical Effectiveness Pharmacist, NEW Devon CCG presented an evidence review. Specialists were unable to attend the meeting however written feedback had been received.

Lisdexamfetamine is a stimulant and a pharmacologically inactive pro-drug which converts into dexamfetamine. NICE recommend the stimulant methylphenidate as the first line option for most ADHD patients. In clinical practice, lisdexamfetamine would be an alternative to the current second line non-stimulant atomoxetine and to the stimulant dexamfetamine. NICE are expected to initial a review of Clinical Guidance on the management of ADHD (CG 72) in July 2014.

The committee reviewed the evidence for commissioning lisdexamfetamine as an alternative second line once daily treatment for this indication. Four double-blind parallel-group randomised controlled trials (RCTs) were identified including a head-to-head comparison with atomoxetine and three placebo-controlled trials, one of which had a methylphenidate reference arm. No published clinical trials or comparative analysis were identified comparing lisdexamfetamine with dexamfetamine. All trials were conducted in children and/or adolescents with symptoms of at least moderate severity.

The RCT comparing lisdexamfetamine and atomoxetine in patients with inadequate response to a previous course of methylphenidate had a primary endpoint of time to first clinical response defined by a CGI-I score of 1 or 2. Superior outcomes were reported for lisdexamfetamine with regard to the median time to first clinical response, the proportion of patients achieving a clinical response and improvement in symptoms. A European placebo-controlled trial which included methylphenidate as a reference arm found a mean change in ADHD-RS-IV significantly greater for lisdexamfetamine and methylphenidate compared to placebo. For patients with a history of methylphenidate use the mean change from baseline in ADHD-RS-IV total score was comparable with that of the total study population. 45% of the study population had no previous treatment for ADHD. Significantly more patients treated with lisdexamfetamine and methylphenidate had very much improved or much improved CGI-I scores compared to placebo. Post-hoc analysis of outcomes for lisdexamfetamine and methylphenidate for the total population reported superior outcomes for lisdexamfetamine-treated patients. A randomised placebo-controlled withdrawal study was conducted following an extension to the European trial; significantly fewer patients receiving lisdexamfetamine met the treatment failure criteria than placebo treated patients. Outcomes from other placebo controlled trials were similar to those of the European study but a post-hoc analysis of one trial indicated that less than 10% of patients had previously been treated with methylphenidate.

Budget impact analyses indicate that at the population level lisdexamfetamine is broadly comparable in cost to atomoxetine. This takes into account the extent of twice daily dosing with atomoxetine locally. There is insufficient local clinical experience with dexamfetamine to estimate the optimal dose. If all patients require doses of dexamfetamine at the usual upper limit (as per costs in NICE TA), lisdexamfetamine is more expensive than dexamfetamine tablets and less expensive than dexamfetamine syrup.

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

- Lisdexamfetamine is a stimulant similar to the existing first line treatment. Feedback from a local specialist indicated that most patients switch from methylphenidate to a second-line option because of problems with tolerability. Lisdexamfetamine has a very similar side effect profile to methylphenidate therefore may not be the most clinically appropriate second-line choice
- Better compliance is expected with this drug than dexamphetamine as it is a once daily medication.
- Lisdexamfetamine is considered to have less potential for abuse than dexamfetamine.
- Costs – comparable costs to existing treatment at the population level.
- Local specialists have indicated that only small numbers of patients would be expected to be treated with lisdexamfetamine.

The committee voted 4 to 2 in favour of commissioning lisdexamfetamine for this indication.

ACTION: Commissioning policy to be published.

4. Dilatation and curettage for dysfunctional uterine bleeding

As part of the work being undertaken to align commissioning polices across Devon consideration had been given to dilatation and curettage for dysfunctional uterine bleeding. Hilary Pearce – Clinical Effectiveness Pharmacist, NEW Devon CCG presented a paper.

NHS Plymouth Clinical Effectiveness Commissioning Group approved a policy on the use of dilatation and curettage for dysfunctional uterine bleeding in July 2009. The policy stated that dilatation and curettage is not an evidence-based procedure for the under 40 age group for management of dysfunctional uterine bleeding. NHS Devon and Torbay Care Trust did not have a policy for this condition.

The NHS Plymouth policy is not supported by the NICE clinical guideline on heavy menstrual bleeding. The clinical lead for menstrual disturbances at Derriford Hospital, Plymouth has advised that simple dilatation and curettage has become almost completely obsolete and has "disappeared" from clinical practice. Therefore it is recommended that the existing NHS Plymouth policy should be rescinded.

ACTION: NHS Plymouth policy on dilatation and curettage to be rescinded.

5. Local Medicines Evaluation in Service Proposals

Jo Roberts presented a paper setting out the rationale for establishing a local position for in-tariff drugs for use under a 'Medicines Evaluation in Service' where routine commissioning had not been accepted by commissioners but a provider organisation was willing to support a consultant to gain some experience of use in special clinical circumstances.

Prescriptions would be funded and approved by the prescribing clinician's organisation on a limited individual basis. GPs would be informed of decisions and the rationale for them but not asked to prescribe non-commissioned medication. This solution would provide a transparent process, an opportunity to gain greater individual clinician experience and regular follow-up, an opportunity for organisational scrutiny and potential peer review of appropriateness. If a particular drug was found to have a wider value than suggested by current research evidence it could be identified as needing further formal research or resubmission to CPC.

The Clinical Effectiveness Governance Manager had contacted secondary care pharmacists who had provided comments on the paper:

- South Devon Healthcare NHS Foundation Trust and Royal Devon and Exeter NHS Foundation Trust have confirmed their agreement with the proposal.

- North Devon Healthcare NHS Trust has advised that although there might be an odd occurrence this is dealt with through the Prescribing Interface Group. Drugs are either moved to formulary status or taken to the local Drug and Therapeutics committee for evaluation as to status. This ensures that the formulary remains reasonably strict by that there is a mechanism for the use of non-formulary drugs.

The committee discussed a number of issues pertinent to this proposal these included:

- That there are difficulties associated with prescribing non-formulary drugs both in the actual prescribing process and in the availability of non-formulary drugs at some hospital outpatient pharmacies. It was noted that although South Devon Joint Formulary and the Plymouth Area Joint Formulary share similar approaches their merger has identified a difference in practice in the local application of the formularies. Neither method of applying the formulary is right nor wrong; both have merits and faults.

- Patient experience/patient choice – outpatient pharmacies are very busy and patients can experience delays. In some cases patients are going to their GPs for prescriptions rather than going to hospital outpatient departments. The need for patients to feel confident when they are prescribed off-formulary drugs was identified. It was noted that all the drugs are licenced for use and that patients can ask questions if they have concerns. Some members questioned if another committee would be another hurdle for patients?

- The role of the Clinical Policy Committee is to make decisions for the whole population of Devon. Exceptional Treatment Panels make decisions for individual patients for drugs which are not included in local formularies and clinicians feel their patient would benefit. Its role is to approve funding. In the case of drugs which are in tariff no additional funding is transferred to the provider. Thus providers have to consider the merits of approval by panel or approval by a process managed within the hospital.

- It would be helpful if all trusts had the same process for the use of off formulary drugs.

- This is currently an outline of the principle. Detailed work up of documentation, reporting and communication would be needed.

It was agreed that the Local Medicines Evaluation in Service proposal would be raised with Dr Tim Burke, Chair of NEW Devon CCG.

ACTION: Local Medicines Evaluation in Service proposal to be raised with Dr Tim Burke.

The committee agreed that the development of the proposed Local Medicines Evaluation in Service proposal should be taken forward.

ACTION: Development of the Local Medicines Evaluation in Service proposal to be taken forward.

6. Clinical Policy Committee Annual Report 2013 – 14

The committee were asked to receive the first annual report of the CPC. The report provided a comprehensive account of the work of the committee in 2013 – 14 and the governance and operational arrangements underpinning the meetings.

Over the past year the committee has met 7 times and 22 commissioning policy decisions have been taken. These included putting in place 15 commissioning policies/policy statements, taking 5 decisions not to routinely commission and 2 decisions to formally revoke old policies superseded by NICE. As part of this work 3 policies were reviewed in respect of the policy harmonisation work programme (circumcision, Dupuytren's contracture and focal hyperhidrosis). Other topics within this work programme have been brought to the committee for discussion and it was agreed that no formal commissioning position was required. These included areas which are now the commissioning responsibility of NHS England (dental implants, planned treatment abroad, intrathecal baclofen for severe spasticity in adults) and where a local policy was not needed (laser surgery for short sight, multiple chemical sensitivity, urinary catheterisation).

The committee has been mindful of the need to be cost conscious with meeting organisation and has sought to rotate meeting venues across the CCG's footprint. Venues are either NHS facilities or those of strategic partners, keeping costs to a minimum.

A process for Declarations of Interest has been formalised and a confirmed appeals process, communication framework, publication process and robust governance arrangements are in place.

Further public representation has been secured following a process of lay engagement. There are now two lay members to the committee.

Reflective practice and on-going development have included changes to the Terms of Reference in respect of learning from reflective practice and committed time for committee development sessions.

The Governing bodies of NEW Devon CCG and South Devon and Torbay CCG will be asked to accept and ratify the annual report and endorse the role of the committee. The report will be published once ratified.

ACTION: Governing bodies of NEW Devon CCG and South Devon and Torbay CCG to be asked to accept and ratify the annual report and endorse the role of the committee.

ACTION: Ratified report to be published.

The committee discussed a number of issues pertinent to the annual report. The points raised included:

- Development of a process for non-attendance and clarification of an acceptable level of non-attendance by a committee member.

ACTION: Process for non-attendance of committee members and clarification of acceptable levels of non-attendance to be developed.

- It was noted that the role and functions of lay members had not been included in the committee's Terms of Reference. It was agreed that this should be included and that Malcolm Merrett and Jono Broad would discuss and produce a list of functions for inclusion.

ACTION: MM and JB to discuss and produce a list of the functions of lay members for inclusion in the Committee's Terms of Reference.

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

Three NPAG meetings had taken place since the Clinical Policy Committee meeting held on March 2014. The committee received a summary of the NICE guidance discussed.

The committee discussed CCG processes to handle NICE guidance and how assurance was provided with regard to trusts compliance. It was noted that as part of the assurance process Trusts are contacted by the Clinical Effectiveness Governance Manager with regard to the implications of the guidance and their compliance. A spread sheet of responses is maintained and non-responding trusts are followed up. It was agreed that a copy of the spread sheet would be brought to a future CPC meeting.

ACTION: Copy of spread sheet containing details of NICE guidance discussed at NPAG and responses from Trusts to be brought to a future CPC meeting.

8. Any other Business

Exogen Ultra-sound Bone Healing (MTG12) - update

At the meeting held on 7th May 2013 the committee had been asked to consider the evidence on the effectiveness of exogen ultrasound for non-union long bone fractures in comparison to surgery. The committee had agreed that exogen ultrasound should be commissioned in line with NICE MTG12 and that the committee would review the number of Individual Funding Panel (IFP) requests made for treatment to be given outside this policy over the next twelve months.

The committee received a summary of cases considered by the IFP since May 2013:

- 6 cases had been considered during this time.
- 1 case had been approved for a patient who met the policy criteria for exogen.
- 5 cases had not been approved. 2 of these cases had not met the nine month waiting period criteria and had no exceptionality, 3 cases did not involve a long bone and there was insufficient evidence of effectiveness in their conditions.
- 3 further requests for exogen have recently been received. These were reviewed by the IFP on 29 May 2014. None of these requests were approved for similar reasons of not meeting the 9 month criteria or not involving long bones. There has been an increase in the number of requests for exogen before the 9 month waiting period and for use in other indications.

If specialists wish to use Exogen Ultra-sound Bone Healing in other indications they would need to submit evidence to support this use before consideration of any review by CPC.

Summary of actions

	Action	**Lead**
14/04	Lisdexamfetamine for ADHD in children and adolescents commissioning policy to be published.	Rebecca Heayn
14/05	Existing NHS Plymouth policy on dilatation and curettage to be rescinded.	Rebecca Heayn
14/06	Local Medicines Evaluation in Service proposal to be raised with Dr Tim Burke	Chris Roome /Jo Roberts
14/07	Development of Local Medicines Evaluation in Service proposal to be taken forward.	Chris Roome /Jo Roberts
14/08	Governing bodies of NEW Devon CCG and South Devon and Torbay CCG to be asked to accept and ratify the annual report and endorse the role of the committee.	Rebecca Heayn
14/09	Ratified Annual Report to be published.	Rebecca Heayn
14/10	Process for non-attendance/acceptable level of attendance by committee members to be developed.	Chris Room/Jo Roberts
14/11	Functions of lay board members to be discussed and list of functions to be produced for inclusion into the Committee's Terms of Reference.	Jono Board/ Mac Merrett
14/12	Copy of spread sheet containing details of NICE guidance discussed at NPAG and responses from Trust to be brought to a future CPC meeting.	Rebecca Heayn