Northern, Eastern and Western Devon
Clinical Commissioning Group

South Devon and Torbay
Clinical Commissioning Group

Clinical Policy Committee

Minutes

Wednesday 24 May 2017, 9.30am to 12.30pm

Committee Suite, County Hall, Exeter

Present:

Dr Jo Roberts* (Chair)	GP Clinical Commissioner	South Devon & Torbay CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Dr Andrew Craig*	GP Clinical Commissioner	NEW Devon CCG
Richard Croker*	Head of Medicines Optimisation Northern and Eastern Localities	NEW Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Paul Foster	Chief Pharmacist	T&SD NHS FT
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	T&SD NHS FT
Barbara Jones	Head of Locality Contracting	NEW Devon CCG
Emma Kain	Public Health Representative	Devon County Council
Mac Merrett	Lay Public Member	
Chris Roome*	Head of Clinical Effectiveness	NEW Devon CCG
Dr Alison Round*	GP Clinical Commissioner	NEW Devon CCG
Mark Taylor	Lay Public Member	
Dr Ben Waterfall*	GP Clinical Commissioner	NEW Devon CCG

Guests:

Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Hannah Jones	Healthcare Evidence Reviewer	NEW Devon CCG
Mr Chris Oppong	Consultant Colorectal Surgeon	Plymouth Hospitals Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Naomi Scott	Healthcare Evidence Reviewer	NEW Devon CCG
Professor Adam Zeman	Professor of Cognitive and Behavioural Neurology	University of Exeter Medical School/ Royal Devon and Exeter 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

1. Welcome and introductions

Attendees were welcomed to the meeting.

The chair welcomed Mark Taylor the new lay public member to the group.

Apologies

Glen Allaway	GP Clinical Commissioner	NEW Devon CCG
Lucy Harris	GP Clinical Commissioner	South Devon & Torbay CCG
Miles Earl	Contract Accountant	NEW Devon CCG
Simon Polak	Deputy Chief Nursing Officer	NEW Devon CCG

Richard Croker, Dr Tawfique Daneshmend and Dr Andrew Gunatilleke left the meeting after the discussion of Lecicarbon A suppositories for constipation.

Confirmation of voting members and representatives

The seven voting members present were identified.

Dr Glen Allaway had deputised voting to Richard Croker
Dr Lucy Harris had deputised voting to Chris Roome

Dr Emma Kain attended as public health representative.

Declarations of interest

Declarations of Interest were collected. The chair reviewed the Declarations of interest. All Declarations of interest are reported in the minutes.

Notification of Any Other Business

Members were asked if they had any items of AOB to discuss. One item of AOB was identified.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Sodium oxybate for narcolepsy with cataplexy	**UCB Pharma Ltd**
Lecicarbon A suppositories for constipation	**Aspire Pharma Ltd**
Alternative treatments:	
Glycerol suppositories	various manufacturers
Sodium citrate micro enemas (Microlette®, Micralax®, Relaxit®)	various manufacturers **Pinewood Laboratories Ltd, RPH Pharmaceuticals Ltd, Focus Pharmaceuticals, Crawford Healthcare**
Phosphate enemas (Cleen®, Fleet®)	various manufacturers **Casen Recordati SL, Fleet Laboratories**
Lubiprostone (Amitizia®)	**Takeda UK Ltd**
Prucalopride (Resolor®)	**Shire Pharmaceuticals Ltd**

NAME OF ATTENDEE	ROLE	
Mr Chris Oppong	Consultant Colorectal Surgeon	Aspire provided lunch for Pelvic Floor MDT during product launch. Aspire provided lunch during BSUG accreditation.
Professor Adam Zeman	Professor of Neurology	While I have no material interest as defined above, UCB sometimes sponsor a meeting of which I am the course director (The British Neuropsychiatry Association Training Weekend for Specialist Registrars in Neurology and Psychiatry).

2. Minutes of the meeting held on 18th January 2017 and matters/actions arising

The minutes of the meeting held on 18th January 2017 were approved.

Summary of actions		
	Action	**Lead**
16/14	*Policy recommendation and QEIA for Guanfacine (Intuniv®) for attention deficit hyperactivity disorder (ADHD) in children and adolescents to be prepared and subsequently progressed to final CCG approval and communication.* Sign off is expected from the executive committee of NEW Devon CCG on the 18th January 2017 and from the executive committee of South Devon and Torbay CCG's on the 19 January 2017. Action complete	
16/15	*Policy recommendation and QEIA for Dexamethasone intravitreal implant (Ozurdex®) for the treatment of non-infectious posterior uveitis to be prepared and subsequently progressed to final CCG approval and communication.* Sign off is expected from the executive committee of NEW Devon CCG on the 18th January 2017 and from the executive committee of South Devon and Torbay CCG's on the 19 January 2017. Action complete	
16/16	*Policy recommendation and QEIA for Botulinum Toxin A for the management of blepharospasm and for the management of hemifacial spasm to be prepared and subsequently progressed to final CCG approval and communication.* Sign off is expected from the executive committee of NEW Devon CCG on the 18th January 2017 and from the executive committee of South Devon and Torbay CCG's on the 19 January 2017. Action complete	

17/01	Policy recommendation and QEIA for Ulipristal acetate 5mg tablets (Esmya®) for intermittent treatment of moderate to severe symptoms of uterine fibroids in line with NICE CG44 to be prepared and subsequently progressed to final CCG approval and communication. Action complete	
17/02	Policy recommendation and QEIA for Brivaracetam (Briviact®) for epilepsy to be prepared and subsequently progressed to final CCG approval and communication. Action complete	
17/03	Production of papers for discussion items: The need for full evidence assessments to be produced for straightforward decisions to be discussed with Jo Roberts. A discussion had taken place. It was noted that some topics for consideration were not as straight forward as they initially appear. A brief scoping exercise may be undertaken to identify the way forward. Action complete	

3. Sodium oxybate for narcolepsy with cataplexy

The CCGs in Devon adopted a number of commissioning policies from their predecessor commissioning organisations including that for sodium oxybate for narcolepsy with cataplexy. NHS England is the responsible commissioner for treatment of this condition in children. In December 2016 they published a clinical commissioning policy for sodium oxybate for symptom control of narcolepsy with cataplexy in children meeting certain criteria. CCGs are the responsible commissioners for the treatment of adults. Under current policy the CCGs do not routinely commission this technology. In light of NHS England's decision the committee are asked to make a recommendation on the CCGs commissioning position for sodium oxybate for narcolepsy with cataplexy in adults. Matt Howard, Clinical Evidence Manager, NEW Devon CCG presented an evidence assessment. Professor Adam Zeman, Professor of Neurology, University of Exeter Medical School and Royal Devon & Exeter NHS Foundation Trust took part in the discussion of this item.

Narcolepsy is a sleep disorder characterised by excessive daytime sleepiness associated with irresistible attacks of sleep, cataplexy, disrupted nocturnal sleep, hypnagogic hallucinations, hypnopompic hallucinations, abnormal rapid eye movement, and sleep paralysis. Cataplexy is characterised by a sudden, usually bilateral, partial or complete loss of muscle tone triggered by emotional stimuli. Cataplexy is thought to affect up to 75% of people with narcolepsy. There is currently no cure for narcolepsy with cataplexy, and most children treated under the NHS England criteria are likely to require lifelong treatment with sodium oxybate. Sodium oxybate is a central nervous system depressant, licensed for the treatment of narcolepsy with cataplexy in adult patients.

Evidence from meta-analyses of RCTs comparing sodium oxybate to placebo demonstrates an improvement in some of the major symptoms of narcolepsy with cataplexy. These benefits are supported by additional data from open-label extension studies. A post-hoc analysis of health related quality of life data collected during an RCT suggests improvements in some domain scores when sodium oxybate is compared to placebo. Whilst study withdrawals due to adverse events were reported to be less than 10% of participants, there are a number of special warnings and precautions for the use of sodium oxybate; notably the risk of respiratory depression, neuropsychiatric side effects, incontinence, and sleep walking.

No relevant published health-economic analyses were identified, and an absence of health-related quality of life data for patients meeting NHS England baseline and "response"

criteria mean that further novel cost-effectiveness modelling is not possible. The Clinical Effectiveness team estimated that in Devon eight patients would receive treatment. Assuming 'average' doses of medication, annual additional medication costs of around £70,000 would be expected (£52,500 for NEW Devon CCG; £17,500 for South Devon and Torbay CCG).

The committee were asked to make a recommendation on whether sodium oxybate should be routinely commissioned in Devon for the treatment of narcolepsy with cataplexy to allow continuation of treatment in individuals reaching 19 years old who had previously been successfully treated with sodium oxybate under the NHS England criteria and in patients aged 19 years and older who meet equivalent criteria.

The committee discussed issues pertinent to this recommendation:

- Specialist opinion stated that narcolepsy with cataplexy has a significant impact on the quality of life of those affected. Those who do not respond to current treatments are unable to attend school or work. Sodium oxybate is the best available treatment. NHS England commission sodium oxybate for patients who have narcolepsy as a result of receiving pandemrix.
- Narcolepsy with cataplexy is a rare condition; CCGs are not usually the commissioners for rare conditions.
- The recent decision by NHS England to fund children meeting their criteria up to nineteen years of age puts the CCGs in a position where they have to review the decision made by the Peninsula Health Technology Group
- No additional cost effectiveness evidence has become available since the original decision was made by the Peninsula Health Technology Group not to routinely commission sodium oxybate for narcolepsy with cataplexy. The cost effectiveness of sodium oxybate in patients meeting the NHS England criteria is not known. It is known that NICE apply a higher threshold than normal to treatments evaluated under its highly specialised technologies programme for rare conditions. If the decision of the committee is not to recommend the routine commissioning of sodium oxybate the rationale is lack of cost effectiveness evidence. The committee accepted that no further evidence is likely to be published.
- The potential for inequity of provision of treatment was discussed, as were the potential for legal challenges and consideration of requests for treatment through the individual funding panel process. For decisions to be legal they must be within the power of the organisation to make, follow correct procedures and not be perverse.
- It was acknowledged that a number of different views existed within the committee and that the committee were being asked to make a recommendation in an unusual situation due to the commissioning position of NHS England.
- Consideration was given to setting different criteria for treatment from those of NHS England. However this was not considered to be the best use of Clinical Effectiveness team time and resources.
- If the position of NHS England changed the CCGs' commissioning position may be reviewed.
- The Chair of the Clinical Policy Committee will write to NHS England regarding the points discussed.

ACTION: Jo Roberts to write to NHS England regarding commissioning of narcolepsy with cataplexy

The committee voted 5 to 2 in favour of recommending Sodium oxybate for the treatment of narcolepsy with cataplexy

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

4. Lecicarbon A suppositories for constipation

A formulary application has been received from Mr Chris Oppong, colorectal surgeon at Derriford Hospital for the use of lecicarbon A suppositories for the treatment of constipation. Hilary Pearce, Clinical Evidence Pharmacist, NEW Devon CCG, presented an evidence assessment. Mr Chris Oppong took part in the discussion of this item.

Lecicarbon A suppositories are indicated as required for the treatment of constipation. They act by releasing carbon dioxide into the rectum thus stimulating a bowel movement. The formulary application proposed that their place in therapy is prior to the use of the prokinetic laxatives, prucalopride and lubiprostone, which are the subject of NICE technology appraisals and as an alternative option to glycerol suppositories, sodium citrate micro-enemas, phosphate enemas and low volume rectal irrigation. During the meeting the specialist present stated that lecicarbon A suppositories would not be considered as alternatives to glycerol suppositories and sodium citrate micro-enema.

Lecicarbon A suppositories were licensed in the UK in 2015 via a procedure for products with well-established use in other EU countries. This procedure does not require a clinical trial development programme; published literature is accepted as supporting evidence for the licensing application.

A clinical trial and a case series have been identified which evaluate the use of lecicarbon A suppositories for constipation in adults. These were published in 1957 and 1974 respectively. There is very limited information in these papers. A literature search for evidence for other types of carbon-dioxide releasing suppositories identified one small placebo-controlled cross-over double-blind randomised trial evaluating the effect of a single suppository in 29 patients. Clinical evidence suggests that approximately 50% of patients achieve bowel evacuation after insertion of a suppository.

With regard to comparator rectal laxatives, a systematic review found no RCTs evaluating the effect of phosphate enemas.

On a single dose basis, lecicarbon suppositories are less expensive than phosphate enemas. They are also considerably less expensive than a trial of lubiprostone or prucalopride. The NICE Technology Appraisals require a two week trial of lubiprostone (TA318, issued 2014) and a four week trial of prucalopride (TA211, issued 2010) before assessing efficacy. The specialist present stated that patients would be offered a 4-6 week trial of lecicarbon A suppositories.

The committee were asked to make a recommendation on the routine commissioning of Lecicarbon A suppositories for constipation.

The committee discussed issues pertinent to this recommendation:

- The opinion of the specialist present was that the treatment of constipation uses a significant amount of NHS resources. The condition is difficult to treat in both secondary and primary care.
- Derriford has a specialist nurse who is able to spend time with patients discussing and optimising their medication and diet. This has had a big impact on the patients' quality of life and significantly reduced the need for surgery.
- Lecicarbon A suppositories would be used to treat patients with slow transit time who do not respond to other laxatives as an alternative to enemas or low volume rectal irrigation. The opinion of the specialist present was that access to lecicarbon as a treatment option may enable discharge of patients from hospital services and reduce the need for pro kinetic laxatives and rectal irrigation.
- It is important that patients with a mechanical blockage are in identified and treated appropriately in secondary care. Lecicarbon A suppositories would be specialist initiated.

The committee voted unanimously in favour of recommending the routine commissioning of Lecicarbon A suppositories for constipation

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

A discussion took place with regard to the route by which Lecicarbon A suppositories for constipation came to the Clinical Policy Committee.

5. Annual Report 2016-17

The committee were asked to receive the fourth annual report of the Clinical Policy Committee (CPC). The report provides a comprehensive account of the work of the committee in 2016 to 2017 and the governance and operating arrangements underpinning the meetings.

NEW Devon CCG and South Devon & Torbay CCG discharge their responsibilities for making local decisions about the funding of medicines and treatments for patients in Devon. Committee meetings are held at intervals of approximately six weeks. Over the past year five meetings have been held. The committee has considered fifteen evidence assessments in respect of drugs and treatments. There is also engagement with local clinical specialists as part of the assessment process, and they are invited to attend to contribute to discussions.

There have been some membership changes during the year. Due to changes at GP practices and other commitments, three voting members stepped down from the committee during the year. The committee were pleased to welcome Dr Lucy Harris and Dr Glen Allaway as new members; a vacancy still remains for the Western locality, NEW Devon CCG.

In addition to the voting members, the committee is supported by advisory members. This includes two lay public members, who ensure that the public interest of the local population is represented in discussion and decision making. The committee was sorry that one of the serving lay public members, Jono Board, stepped down from the role in September 2016. Following advertisement of the vacancy we are pleased to welcome Mark Taylor as a new lay public member from 1 April 2017.

The clinical policy engagement and consultation panel continues to support CPC and the CCGs by providing a separate opportunity to reflect on the policy recommendations and consider the public interest issues. They meet approximately two weeks post-CPC to determine the need for any further engagement or formal consultation to be carried out prior to a final decision being taken by the CCGs. This process is lay-member led, supported by the CPC lay public members and the CCGs' Governing Body lay members with a remit for patients and public from each CCG. The process and any resulting engagement or consultation precedes the CCGs' executive decision making groups taking a final decision on whether to accept a clinical policy recommendation.

All policy recommendations have a Quality and Equality Impact Assessment undertaken as an integral step in the process following the recommendation of the committee. These are considered by the clinical policy engagement and consultation panel and submitted to the CCGs along with the final policy recommendation for approval.

Following a review last year, the regular meeting location has been County Hall, Exeter, with all but one meeting being held here. The committee remains mindful of the need to be cost conscious with meeting organisation; all meetings are held in facilities of strategic partners of the NHS.

A committee development session was held in January 2017. In light of the changes in committee membership, this sought to pull key elements of previous development sessions together to give new members an overview of decision making considerations and some greater detail on particular concepts. Existing members also found this a useful refresher and opportunity for discussion. Members reaffirmed that committee development sessions were helpful to their work on the committee and should continue to be held at suitable junctures. Further committee development is therefore planned for 2017-18.

CPC received the report as a record of activity in 2016-17. The report will be submitted to the appropriate groups of both NEW Devon CCG and South Devon & Torbay CCG for information and assurance. It will then be published via the website to ensure it is publicly available.

The committee thanked Rebecca Heayn for producing an excellent annual report.

ACTION: Report to be submitted to the appropriate bodies of the CCGs to be received and ratified.

ACTION: Once ratified the annual report will be published and made publically available via the CCG website.

6. Update from NICE Planning Advisory Group (NPAG)

NPAG meeting 10th January 2017

The committee received an update from the NPAG meeting which had taken place on 10th January 2017.

NPAG meeting 7th March 2017

The committee received an update from the NPAG meeting which had taken place on 7th March 2017.

It was noted that a piece of work is being undertaken through the Sustainability and transformation plan (STP) with regard to a commissioning position for GreenLight XPS for treating benign prostatic hyperplasia (MTG29).

An annual report has been produced for NPAG. It was suggested that a summary be produced for CPC.

ACTION: Summary of NPAG annual report to be produced for CPC.

7. Update from Clinical Policy Engagement and Consultation Panel

The committee received the minutes of the Clinical Policy Engagement and Consultation Panel meeting which took place on Wednesday 1 February 2017.

It was reported that the group had considered two policy recommendations from the Clinical Policy Committee meeting held on 18th January 2017 and agreed that no further engagement or public consultation action was required.

Mark Taylor had joined the panel as a lay public member representative of the Clinical Policy Committee.

The annual report for the Clinical Policy Engagement and Consultation Panel has been produced by Rebecca Heayn and will be presented to the panel at their next meeting and following approval to CPC.

The next meeting of the Clinical Policy Engagement and Consultation Panel will take place on Wednesday 7th June 2017.

8. Date of next meeting
note change of venue and start time

The next meeting of the Clinical Policy Committee will be held on **Wednesday 26th July**. Due to renovation work being undertaken in the Committee Suite at County Hall, Exeter the committee were asked to note the change of venue and later start time:

Venue: **The Watermark, Ivybridge**
Commencing at: **10.00 am**

9. Any other business

Completion of Declaration of Interests Form

A query was raised with regard to whether an e-mail of confirmation that a member of the committee did not have any declarations of interest could be accepted without the need to attached a completed Declaration of Interests form.

It was agreed that the clinical effectiveness team would seek clarification. Currently, the completed Declaration of Interests form should be e-mailed to the Clinical Effectiveness team from the committee members e-mail account.

ACTION: Rebecca Heayn to seek clarification on the corporate governance requirements in respect of receipt of Declarations of Interest.

Summary of actions

	Action	**Lead**
17/04	Letter to be written to NHS England regarding commissioning of narcolepsy with cataplexy	Jo Roberts
17/05	Sodium oxybate for narcolepsy with cataplexy: policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
17/06	Lecicarbon A suppositories for constipation: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
17/07	CPC Annual report to be submitted to the appropriate bodies of the CCGs to be received and ratified.	Rebecca Heayn
17/08	Once ratified the CPC annual report will be published and made publically available via the CCG website.	Rebecca Heayn
17/09	Summary of NPAG Annual Report to be produced for CPC.	Fiona Dyroff
17/10	Clarification to be sought on the corporate governance requirements in respect of receipt of Declarations of Interest.	Rebecca Heayn