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

Clinical Policy Committee (CPC)
Minutes

Wednesday 18 January 2017, 9.30 am to 12.30

Committee Suite, County Hall, Exeter

Present:

Dr Alison Round (Chair)*	GP Clinical Commissioner	NEW Devon CCG
Dr Glen Allaway*	GP Clinical Commissioner	NEW Devon CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Rob Cowdry	Contracts Governance Manager	NEW Devon CCG
Dr Andrew Craig*	GP Clinical Commissioner	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
Dr Lucy Harris*	GP Clinical Commissioner	South Devon & Torbay CCG
Andrew Kingsley	Patient Safety and Quality	NEW Devon CCG
Mac Merrett	Lay Member	
Sarah Ogilvie	Acting Consultant in Public Health	Devon County Council
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG
Dr Ben Waterfall*	GP Clinical Commissioner	NEW Devon CCG

Guests:

Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Mr Ben Peyton-Jones	Consultant Obstetrician and Gynaecologist	Royal Devon & Exeter NHS FT
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Dr Martin Sadler	Consultant Neurologist	Plymouth Hospitals NHS Trust
Mr Peter Scott	Consultant Obstetrician and Gynaecologist	Plymouth Hospitals NHS Trust

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 joint meeting by teleconference

1. Welcome and introductions

Apologies

Dr Jo Roberts	GP Clinical Commissioner and Committee Chair	South Devon & Torbay CCG
Richard Croker	Head of Medicines Optimisation Northern and Eastern Localities	NEW Devon CCG
Miles Earl	Contract Accountant	NEW Devon CCG
Samantha Morton	Head of Contracting & Procurement	South Devon & Torbay CCG

Dr Jo Roberts had deputised voting to Paul Foster
Sarah Ogilvie attended the meeting as representative for Public Health
Rob Cowdry attended the meeting as deputy for Barbara Jones

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. All Declarations of Interest are reported in the minutes

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Ulipristal acetate 5mg tablets (Esmya®) **for intermittent treatment of moderate to severe symptoms of uterine fibroids in line with NICE CG44**	**Gedeon Richter (UK) Ltd**
Alternative treatments:	
Surgical treatment (myomectomy, uterine artery embolization, transcutaneous resection of fibroid, morcellation, endometrial ablation, hysterectomy)	As a private provider of surgical treatments for patients with uterine fibroids
Brivaracetam (Briviact®) **for epilepsy**	**UCB Pharma Limited**
Alternative treatments for epilepsy:	
Eslicarbazepine (Zebinix®)	**Eisai Ltd**
Lacosamide (Vimpat®)	**UCB Pharma Ltd**
Phenobarbital (generic)	**Various manufacturers**
Phenytoin (Epanutin® and generic)	**Pfizer UK Ltd and various manufacturers**
Pregabalin (Lyrica® and others)	**Pfizer UK Ltd and various manufacturers**
Tiagabine (Gabitril®)	**Cephalon UK Ltd**
Vigabatrin (Sabril®)	**Sanofi**
Zonisamide (Zonegran®)	**Eisai Ltd**
Retigabine (Trobalt®)	**GlaxoSmithKline UK**
Perampanel (Fycompa®)	**Eisai Ltd**

NAME OF ATTENDEE	ROLE	
Mr Ben Peyton-Jones	Consultant Obstetrician and Gynaecologist	*Work as paid adviser to above manufacturing company* Espiner Medical (Surgical device) *In receipt of equipment manufacturing company/ companies.* Surgical device

		In receipt of lecture fees in excess of £150 in the last year from above pharmaceutical/ manufacturing company/companies. Espiner Medical (Surgical device) – running course on Sub-total hysterectomies
Dr Martin Sadler	Consultant Neurologist	• *Received gifts, benefits or sponsorship of any kind, whether refused or accepted work over £25 or several small gifts worth a total of over £100 form the above or closely related pharmaceutical / manufacturing company/companies.* • *Hospitality received where the drug(s) /device(s)/intervention(s)/treatment(s) under consideration were discussed by a representative of a drug/manufacturing company/companies.* • *Any of the above interests for a competitor of this drug/device/intervention.* Department has received support for academic meetings and regional study days for trainees from several drug companies including UBC. I have received an honorarium for chairing part of an epilepsy meeting that was sponsored by UCB. I have agreed to speak at a further meeting sponsored by UCB in 2017. I have spoken at a national academic meeting where the drug stands included one sponsored by UCB. Other drug companies that make AEDs and drugs for other neurological diseases were also present at the regional and national meetings. I have collected data for a study on perampanel and I am collecting data for a study on lacosamide and other AEDs but this is not a commercially sponsored study. I am a PI in SANAD 2 a non-commercial sponsored trial of a range of AEDs.

2. Minutes of the meeting held on 23rd November 2016 and matters arising

The minutes of the meeting held on 23 November 2016 were approved.

Summary of actions		
	Action	**Lead**
16/11	*Policy recommendation and QEIA for Ivermectin (Soolantra®) for Rosacea to be prepared and subsequently progressed to final CCG approval and communication.* *Awaiting approval of QEIA prior to publication.* This policy was published on 29 November 2016. Action complete.	
16/12	*Policy recommendation and QEIA for Linaclotide (Constella®) for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults to be prepared and subsequently progressed to final CCG approval and communication.* *Awaiting approval of QEIA prior to publication.* This policy was published on 29th November 2016. Action complete.	
16/13	*Policy recommendation and QEIA for surgery for Ganglion Cyst to be prepared and subsequently progressed to final CCG approval and communication.* *Awaiting confirmation of implementation date from DRSS prior to publication.* This policy was published on 23 December 2016. Action complete.	
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.	Rebecca Heayn
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.	Rebecca Heayn
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.	Rebecca Heayn

16/17	*Specialist engagement with processes of the clinical policy committee – trust chief pharmacists and Drug and Therapeutic Committee chairs or equivalent be added to distribution lists and thereby notified of any formulary applications received.* Acute trust Chief Pharmacists and Drug and Therapeutic Committee Chairs have been added to the distribution lists. Action complete.	

3. Ulipristal acetate 5mg tablets (Esmya®) for intermittent treatment of moderate to severe symptoms of uterine fibroids in line with NICE CG44

In April 2016 Ulipristal acetate (UPA) 5mg tablets (Esmya®) were considered by CPC for use as an alternative to surgery for the treatment of intermittent moderate to severe symptoms of uterine fibroids in three distinct cohorts of women. No limit on the number of courses was considered. At that time, routine commissioning in Devon was not accepted, principally due to uncertainties in cost-effectiveness and financial impact. Since then, NICE have issued a revised clinical guideline for heavy menstrual bleeding (HMB) which now includes recommendations for the use of up to four courses of ulipristal for intermittent treatment of fibroids. A re-application has been submitted for use of ulipristal for up to four courses in line with NICE CG44. Matt Howard, Clinical Effectiveness Manager, NEW Devon CCG presented a paper. Mr Peter Scott, Consultant Obstetrician and Gynaecologist, Plymouth Hospitals NHS Trust joined the meeting for discussion of this item. Mr Ben Peyton-Jones Consultant Obstetrician and Gynaecologist, Royal Devon and Exeter NHS Foundation Trust joined the discussion of this item via teleconference.

Uterine fibroids are commonly treated surgically; symptomatic uterine fibroids are one of the leading reasons for hysterectomy. Other less invasive procedures may preserve fertility; however these do not offer a definitive cure. For their guideline update, NICE included the same three RCTs that were considered by CPC in April 2016.

NICE state that high quality data were only available for one critical outcome: menstrual blood loss; this evidence favoured ulipristal acetate over placebo. Moderate quality evidence also favoured ulipristal acetate in terms of fibroid volume, but the difference was of uncertain clinical importance. There was high quality evidence of no clinically important difference in quality of life and menstrual blood loss between UPA 5mg/d and leuprorelin acetate over three months. NICE concluded that evidence on the long-term effectiveness of ulipristal acetate was uncertain because of the lack of evidence on benefits and harms of more than four cycles. NICE recommend ulipristal for up to four courses based on efficacy and safety data from the included studies.

Cost utility analyses submitted to the Scottish Medicines Consortium (SMC) and the All Wales Medicines Strategy Group (AWMSG) suggest ulipristal would be considered cost-effective compared to invasive procedures, or no treatment in a variety of scenarios. These analyses are subject to a number of limitations, and plausible scenarios resulted in incremental cost-effectiveness ratios (ICERs) above the threshold usually accepted when considering cost effective use of resources in the NHS; however both organisations accepted ulipristal for intermittent treatment of fibroids.

NICE subsequently developed a novel health economic model which suggests that ulipristal is cost effective at usual thresholds compared to no treatment for women with HMB and fibroids 3 cm or more in diameter who are not currently considering invasive procedures. Whilst this restricted cohort does not represent the broader population of women who may be offered ulipristal for the intermittent treatment of fibroids, NICE considered the model to be sufficient to recommend ulipristal for general use.

Budget impact models presented at the time of the original CPC decision suggested that commissioning ulipristal for the intermittent treatment of fibroids may be cost saving for one or two years of treatment, but would ultimately cost the local health economy more if treatment continued beyond two years. For this re-application, budget impact models constructed by NICE and by Gedeon Richter limit the number of courses of ulipristal. These models consider different patient groups and result in differing estimates of the direction and magnitude of the financial impact of

commissioning ulipristal in line with NICE CG44. The budget impact is therefore subject to significant uncertainty, depending on resulting clinical use.

NICE consider a local cohort of 18-55 year old women not considering surgery; for these women, intermittent use of ulipristal represents a new treatment option, albeit at an increased cost to the local health economy. Gedeon Richter consider a local cohort of women aged 46-50 who would otherwise undergo a surgical procedure. For these women, ulipristal represents a treatment with a lower acquisition cost if treatment is limited to four intermittent courses. It is uncertain which patient group will receive UPA 5mg in routine clinical practice, and whether the maximum four cycles recommended by NICE will be observed. Overall, the patient cohort is likely to include women from both groups. Considering both models, the use of intermittent courses of ulipristal may result in a Devon-wide financial impact of between an annual increase of up to £42,000, and a saving of up to £110,500 (over 20 months).

The committee discussed issues pertinent to this recommendation:

- UPA is effective and local specialist opinion is that it should be available as an option for patients who do not want surgery in order to help them reach the menopause. It is particularly useful for high risk patients where avoiding surgery is a priority.
- The committee expressed concern that patients may receive far more than the recommended four courses of UPA to manage their ongoing symptoms. Specialists stated that treatment would primarily be started in women approaching the menopause where four courses will prove sufficient and that NICE limit the number of courses to four. Patients who have received UPA have not asked for more than four courses and are not coming back for surgery. Younger patients are often looking for longer term definitive solutions.
- Treatment can cause endometrial thickening but papers do not suggest a risk of endometrial cancer. From limited experience gained so far, specialists reported that patients usually underwent ultrasound scan at 6 months to check for any endometrial changes. In time more will be known about the longer term side effects.
- The alternative medical treatments with injectable Gonadotrophin Releasing Hormone analogues (GnRHa) have more side effects including osteoporosis and are only licensed for six months. For a patient who suffers side effects the advantage of UPA is that they can stop the tablets whereas once the GnRHa injection is given it acts for a month.
- Current practice for pre-operative use is for the specialist to initiate and the GP to prescribe month two and three. A similar arrangement could operate for intermittent use.
- UPA is included in NHS choices and patients are aware of it.

The committee voted unanimously in favour of recommending Ulipristal acetate 5mg tablets (Esmya®) for intermittent treatment of moderate to severe symptoms of uterine fibroids in line with NICE CG44.

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

4. Brivaracetam (Briviact®) for epilepsy

A formulary application has been received from Dr Martin Sadler, consultant neurologist at Derriford Hospital with support from other neurologists at the hospital, for the use of Brivaracetam (Briviact®) for the treatment of epilepsy. Hilary Pearce, Clinical Effectiveness Pharmacist, NEW Devon CCG presented an evidence assessment. Dr Martin Sadler took part in the discussion of this item.

NICE Clinical Guidance for epilepsy (CG137) recommends monotherapy as first line treatment for focal seizures. Adjunctive treatment is recommended if a second well-tolerated anti-epileptic drug (AED) given as monotherapy is ineffective. Brivaracetam is a new AED which is licensed as an adjunctive treatment for partial-onset (focal) seizures.

Three pivotal phase III studies supported the licensing of brivaracetam. In clinical studies, there was no observed benefit of brivaracetam versus placebo in patients taking levetiracetam concurrently. A meta-analysis of outcomes from the phase III studies, excluding patients receiving concomitant levetiracetam, found statistically significant differences between brivaracetam and placebo for 50% reduction in seizure frequency and other efficacy-related outcomes. There are no clinical trials comparing brivaracetam with other anti-epileptic drugs. Four indirect treatment comparisons reported no statistically significant difference in efficacy outcomes and rate of discontinuation due to

adverse events between brivaracetam and comparator AEDs. Brivaracetam would be prescribed in place of an existing AED.

The acquisition cost of brivaracetam is lower than the cost of some comparator AEDs and mid-range for the maintenance dose cost of other comparator AEDs prescribed locally.

The committee were asked to make a recommendation on the use of Brivaracetam (Briviact®) for management of partial-onset seizures.

The committee discussed issues pertinent to this recommendation:

- 30% of patients are not satisfactorily controlled on monotherapy or polytherapy.
- New drugs are used cautiously; initially brivaracetam would only be used for a small group of patients as an adjunctive treatment when other adjunctive drugs have failed. In trials brivaracetam has been shown to work for some treatment resistant patients.
- Finding the right treatment for individual patients is complex. All drugs have interactions and side effects which need to be considered. Brivaracetam will be a useful addition.
- It was noted that because brivaracetam is a newly licenced drug there will not be data available from a pregnancy registry.
- The cost of brivaracetam is similar to current treatments, use should be cost neutral. If the drug is effective there could be a reduction of use of NHS resources as a result of fewer patients presenting to A&E and less GP appointments as a result of effective seizure reduction.
- Because of its place in therapy Brivaracetam will be initiated by specialists and then continued by GPs. The patient's clinical condition will be monitored in a specialist clinic.

The committee voted unanimously in favour of recommending Brivaracetam (Briviact®) for the treatment of epilepsy.

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

5. 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 14th December 2016.

It was reported that the group had considered three policy recommendations from the Clinical Policy Committee meeting held on 23rd November 2016 and agreed that no further engagement or public consultation action was required. The panel had noted that they are more comfortable with decisions made when they are in agreement with NHS Choices and it was suggested that this information be added to the Clinical Policy Committee papers.

6. AOB

Production of papers for discussion items

Production of the Clinical Policy Committee meeting papers is a time consuming process for the Clinical Effectiveness Team. There are occasions when decisions are very straightforward and a full evidence assessment may not be required. The committee discussed issues pertinent to this suggestion:

- Drugs are not licenced unless they have been proven efficacious.
- It was suggested that a triage process be put in place to identify the depth of information needed by the Clinical Policy Committee in order to make a decision.
- The possibility of using Chair's actions to determine if more detailed work is required.
- Some members stated that they did not want to make a 'no' decision on limited evidence.
- It was agreed that Chris Roome would raise the issue with Jo Roberts.

ACTION: Need for full evidence assessments to be produced for straightforward decisions to be discussed with Jo Roberts.

Update on lay member vacancy

The vacancy for a lay member to sit on the Clinical Policy Committee and the Clinical Policy Engagement and Consultation Panel has been re-advertised. Two applications were received, one

applicant has subsequently withdrawn from the process and the remaining candidate will be interviewed in the coming weeks.

7. Committee Development Session

Following the formal meeting a Committee Development Session took place.

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.	Rebecca Heayn
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.	Rebecca Heayn
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.	Rebecca Heayn
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.	Rebecca Heayn
17/02	Policy recommendation and QEIA for Brivaracetam (Briviact®) for epilepsy to be prepared and subsequently progressed to final CCG approval and communication	Rebecca Heayn
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.	Chris Roome