Northern, Eastern and Western Devon
Clinical Commissioning Group

South Devon and Torbay
Clinical Commissioning Group

Clinical Policy Committee

Minutes

Wednesday 23rd May 2018, 9.30 am to 12.30

Committee Suite, County Hall, Exeter

Present:

Dr Jo Roberts (Chair)	Voting Member	South Devon & Torbay CCG
Dr Glen Allaway	Voting Member	NEW Devon CCG
Dr Andrew Craig	Voting Member	NEW Devon CCG
Dr Nick D'Arcy	Voting Member	South Devon & Torbay CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	Royal Devon & Exeter NHS FT
Dr Lucy Harris	Voting Member	South Devon & Torbay CCG
Barbara Jones	Head of Locality Contracting	NEW Devon CCG
Mac Merrett	Lay Public Member	
Tracey Polak	Assistant Director/Consultant of Public Health	Devon County Council
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG
Dr Ben Waterfall	Voting Member	NEW Devon CCG

Guests:

Dr Keith Gilhooly	Consultant Psychiatrist	Devon Partnership Trust
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Graham Simpole	Joint Formularies Support Pharmacist	NEW Devon CCG
Chris Sullivan	Pharmacist	Devon Partnership Trust

In attendance:

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

1. Welcome and introductions

Dr Nick D'Arcy was welcomed to the group as a Voting Member.

Tawfique Daneshmend was thanked for stepping in to chair the meeting held on 21 March 2018 in the absence of Jo Roberts.

Apologies

Richard Croker	Head of Medicines Optimisation	NEW Devon CCG
Paul Foster	Secondary Care Pharmacist	Torbay and South Devon NHS FT
Simon Polak	Deputy Chief Nursing Officer	NEW Devon CCG
Dr Alison Round	GP Clinical Commissioner	NEW Devon CCG
Dr Peter Rowe	Consultant Nephrologist	University Hospitals Plymouth NHS Trust
Mark Taylor	Lay Public Member	

Committee membership updates

Miles Earl, Contracting Accountant Commissioning, NEW Devon CCG had stepped down from the committee and will not be replaced.

Dr Andrew Harrison will be joining the group as a Voting Member. He will attend his first meeting on 18th July 2018.

Confirmation of voting members and Declarations of Interest

The seven voting members present were identified.

Dr Alison Round had requested Chris Roome to deputise as voting member in her absence.

Declarations of Interest were collected. The Chair reviewed the Declarations of Interest. The Declarations made did not result in anyone being excluded from the meeting or from the discussion of any item. 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.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Fluticasone furoate and vilanterol trifenatate (Relvar®, Ellipta®) **combination inhaler for asthma**	**GlaxoSmithKline UK**
Alternative treatments:	
Fluticasone propionate/salmeterol (Aerivio®, AirFluSal®, Sereflo®, Seretide®, Sirdupla®)	**Teva UK Ltd, Sandoz Ltd, Kent Pharmaceuticals Ltd, GlaxoSmithKline UK, Generics UK t/a Mylan**
Fluticasone propionate/formoterol (Flutiform®)	**Napp Pharmaceuticals Ltd**
Beclometasone dipropionate/formoterol (Fostair®)	**Chiesi Limited**
Budesonide/formoterol (Duoresp®, Fobumix®, Symbicort®)	**Teva UK Ltd, Orion Pharma (UK) Ltd, AstraZeneca UK Ltd**

Lurasidone (Latuda®) **for schizophrenia** Alternative treatments: **Haloperidol** **Amisulpride** **Other oral antipsychotics** (aripiprazole, chlorpromazine, clozapine, olanzapine, quetiapine, risperidone, sulpiride, trifluoperazine, zuclopenthixol)	**Sunovion Pharmaceuticals Europe Ltd** **Various manufacturers** **Various manufacturers** **Various manufacturers**

NAME OF ATTENDEE	ROLE	
Keith Gilhooly	Consultant Psychiatrist	On two occasions in the past three years has chaired educational meetings on LAIs on behalf of Lundbeck who make aripiprazole LAI for each chairmanship received £300, but for one occasion the fee was donated directly to charity.

2. Minutes of the meeting held on 21st March 2018 and matters/actions arising

The minutes of the meeting held on 21st March 2018 were approved.

Summary of actions		
	Action	**Lead**
17/14	*Recommended revisions to the CCGs' policy for Cryopreservation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* *The policy recommendation and QEIA have been signed off by the executive committees of NEW Devon CCG and of South Devon and Torbay CCG and is pending publication.* *The recommendation was discussed by the Clinical Policy Engagement and Consultation Panel on 11 October 2017. The panel had not considered that a full public consultation was required. However the panel did feel that people who had material stored should be contacted by letter explaining how the policy affected them to coincide with publication of the policy. A letter has been drafted.* *It has also been raised that letters should be written to the partners of people who have subsequently died but have material stored. A paper is being written for the Strategic Leadership Committee.* *The paper has been written and will be consideration by the Strategic Leadership Committee on 21 March 2018.* The policy has been published. Action complete.	

18/01	*FreeStyle Libre device for interstitial glucose monitoring in diabetes: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* *The policy will be published shortly.* The policy has been published. Action complete.	
18/03	*Intravitreal Bevacizumab for radiation maculopathy - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* The policy will be published shortly.	Rebecca Heayn
18/04	*Intravitreal Bevacizumab for rubeosis iridis and neovascular glaucoma - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* The policy will be published shortly.	Rebecca Heayn
18/05	*Midodrine for orthostatic hypotension due to autonomic dysfunction – form of words to be produced for consideration by the two formulary interface groups in Devon.* This has been added to the Formulary Work Plan along with Parkinson's Disease. Action complete.	Matt Howard
18/06	*The specialist management of abdominal wall hernia in adults – issue of general surgery v specialist surgery to be raised with colorectal surgeons.* A discussion has taken place. The issue is wider than expertise. One surgeon is involved in quality improvement initiatives and is willing to take the issues on and get a consensus and move forward to reduce surgeon numbers from 12 to 6. Will move forward locally in collaboration with NHS Quality Improvement. Action complete.	
18/07	The specialist management of abdominal wall hernia in adults - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication. The policy will be published shortly.	Rebecca Heayn

3. Fluticasone furoate and vilanterol trifenatate (Relvar® Ellipta®) combination inhaler for asthma

An evidence assessment for Relvar Ellipta combination inhaler for asthma was originally presented to the Clinical Policy Committee (CPC) in September 2015 and again in November 2017. At that time the committee voted against the routine commissioning of Relvar Ellipta for Asthma due to limitations in the product licence. However the committee also voted in favour of reconsidering its decision if there were changes to the licence to allow switching from other inhalers. Recently Relvar Ellipta has been licenced for switching in patients already adequately controlled on both inhaled corticosteroid (ICS) and long acting beta2-agonist (LABA). The

decision taken in November 2017 is now being reconsidered. A paper was presented by Matt Howard, Clinical Evidence Manager, NEW Devon CCG.

Relvar Ellipta is a combination dry-powder inhaler containing fluticasone furoate (an ICS) and vilanterol (a LABA). The combination product is available as two different strengths: delivered dose of 92/22mcg and delivered dose of 184/22mcg. The maximum dose when using either strength is one inhalation once daily. Relvar Ellipta is the only ICS/LABA product licensed for asthma which requires once daily inhalation. The 92/22mcg inhaler is routinely commissioned in Devon for use in Chronic Obstructive Pulmonary Disease.

Both strengths of Relvar Ellipta are indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (ICS and LABA) is appropriate: Patients not adequately controlled with ICS and 'as needed' inhaled short acting beta2-agonists (SABA); and patients already adequately controlled on both ICA and LABA

Since Relvar Ellipta for asthma was discussed by CPC in November 2017, no additional efficacy data are available. Direct comparative evidence support non-inferiority of Relvar Ellipta 92/22mcg once daily compared to Seretide Accuhaler 250/50mcg twice daily in terms of lung function; and suggests similarities between the two products in other outcomes such as symptom-free periods and rescue-free periods, asthma control test scores, and quality of life. Indirect evidence from a limited mixed treatment comparison suggests broadly comparable efficacy of Relvar Ellipta once daily to a number of other ICS/LABA combinations.

No relevant new cost-effectiveness analyses for Relvar Ellipta for asthma were found. A cost-minimisation analysis submitted to the All Wales Medicines Strategy Group and the Scottish Medicines Consortium was previously considered by CPC. This assumed comparable efficacy for all comparators and showed Relvar Ellipta would be cost saving compared with a number of alternative ICS/LABA combinations. The results of the model may be out of date, since the acquisition costs of several ICS/LABA preparations have changed since the cost minimisation model was built and additional lower cost ICS/LABA products have come to the market.

There is significant uncertainty in the magnitude of the budget impact of commissioning Relvar Ellipta for patients with asthma. Use in patients requiring a low dose ICS/LABA is likely to be more costly. Assuming equal displacement of other formulary options in this group, costs would increase by an average of around £56.00 per patient per annum. However in patients for whom a medium or high dose ICS/LABA is considered appropriate, Relvar Ellipta is expected to be cost saving. Assuming equal displacement of other formulary options in this group savings of around £80 to £154 per patient per annum are suggested.

Patient numbers are estimated to be around 825 in year 1, rising to around 6,200 in year 5. The proportion of these patients requiring low, medium, or high dose ICS/LABA is not known, limiting the Clinical Effectiveness Team's ability to provide an overall estimate of the budget impact.

It was noted that the role of Relvar Ellipta may be limited by a number of factors including; a lack of fluticasone furoate inhaled monotherapy for asthma (which may affect stepping up/down treatment in line with national and local guidance), questions over steroid dose and a less favourable financial comparison for Relvar Ellipta 92/22mcg compared to low dose ICS/LABA combinations. However the recent extension to the licensed indications and favourable financial comparisons with medium and high dose ICS/LABA combinations suggest an opportunity to reduce expenditure with no loss of efficacy in patients who are established on alternative medium or high dose ICS/LABA inhalers.

The committee discussed issues pertinent to the routine commissioning of Relvar Ellipta combination inhaler for asthma:

- Dr Lee Dobson, Consultant in Respiratory Medicine, Royal Devon and Exeter NHS Foundation Trust was unable to attend the meeting. Dr Dobson had indicated that the routine commissioning of Relvar Ellipta was not expected to result in bulk switching of patients from

alternative ICS/LABA combinations. Switching will be considered when patients have their regular reviews.

The committee voted unanimously in favour of recommending the routine commissioning of the Relvar Ellipta combination inhaler for asthma.

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

4. Lurasidone for schizophrenia

An application has been received for the routine commissioning of lurasidone for schizophrenia. Graham Simpole, Joint Formulary Support Pharmacist, NEW Devon CCG presented an evidence review. The applicant Dr Keith Gilhooly, Consultant Psychiatrist and Christopher Sullivan, Pharmacist, Devon Partnership Trust (DPT) took part in the discussion.

Lurasidone is a second generation atypical antipsychotic and is indicated for the treatment of schizophrenia in adults aged 18 years and over. It is effective in a dose range of 37mg to 148mg once daily with no initial dose titration being required.

Dr Gilhooly has indicated that lurasidone offers a similar side effect profile to aripiprazole with respect to metabolic side effects, and would provide an additional treatment line for patients where metabolic side effects are undesirable, and in whom aripiprazole is ineffective or not tolerated. It has been suggested that amisulpride or haloperidol would be relevant alternatives, as these are considered to have fewer of these metabolic adverse effects than some of the other currently available antipsychotics.

A systematic literature search identified nine Randomised Control Trials (RCTs) of which six were short term and three were long term. All the short term trials compared lurasidone to placebo; three of these also had active reference arms. The three long term RCTs included two comparing lurasidone to active reference comparators and one to placebo alone. Additionally, a six-month, open-label extension study and a network meta-analysis comparing the efficacy and safety of fifteen antipsychotics were identified. The RCTs established that lurasidone displays greater efficacy than placebo although this effect was not consistently demonstrated for each dose in all trials where it was included. One long-term RCT concluded that lurasidone was non-inferior to quetiapine XR whilst another long-term RCT was unable to conclude non-inferiority of lurasidone relative to risperidone, as the number of relapses was much lower than expected.

The network meta-analysis demonstrated that lurasidone was effective compared to placebo. However, five of the comparator antipsychotics, including amisulpride, were shown to be significantly more efficacious, whilst there was no significant statistical difference demonstrated in efficacy with the remaining nine comparators, including haloperidol.

Evidence from a network meta-analysis of clinical trials showed that the effects of lurasidone on blood lipids, glucose and HbA1c were limited; effects on weight gain were moderate; prolactin increase was limited; and lurasidone may prolong QT interval to a lesser extent than most other antipsychotics.

Lurasidone is available in three strengths all of which cost £90.72 for 28 tablets. The annual cost per patient would be approximately £1200 for doses up to 74mg daily and £2400 for the maximum recommended dose of 148mg daily. This compares with an annual price range of about £10 to £640 for amisulpride and about £28 to £580 for haloperidol. Specialists estimate that, there will potentially be 48 patients initiated on lurasidone in Devon in the first year and this will incur an approximate annual cost of between £56,000 and £113,000, depending on the dose of lurasidone. This translates to an estimated budget impact in the range £55k to £85k for lurasidone vs haloperidol and for lurasidone vs amisulpride the budget impact would be in the range £56k to £110k.

The main consideration for lurasidone is that it would provide an alternative option, albeit at considerable additional cost, for patients in whom adverse metabolic side effects are undesirable and where aripiprazole has been ineffective or not tolerated.

The committee discussed issues pertinent to the routine commissioning of lurasidone for schizophrenia:

- Specialists present indicated that there had been a great deal of debate about the side effects associated with most of the currently available antipsychotics. These include increased cardiovascular risk, weight gain and raised prolactin, which can result in long-term wellbeing issues for patients. The specialists stated that medication which raises prolactin levels was generally avoided in people under 25 years of age and young women. Aripiprazole and lurasidone may have an improved metabolic side effect profile compared to other agents. Aripiprazole is the first line antipsychotic. Lurasidone has been available for four years; it is proposed that lurasidone would be used second line after aripiprazole.
- There is uncertainty about the comparative effectiveness of lurasidone. The evidence review suggested it may be less effective than some other antipsychotics based on a network meta-analysis. There was discussion around the reported increase in placebo response over time in antipsychotic drug trials and that this may make it more difficult to show the effectiveness of newer drugs. Further head to head efficacy studies with other antipsychotics would be very helpful. Specialist opinion stated that the difference between the effectiveness of antipsychotics is not felt to be great; lurasidone may be as effective as amisulpride but the side effect profile of lurasidone is better.
- Lurasidone is considerably more expensive than the alternatives however specialists present indicated that savings may be made through increased patient adherence to their medication, better patient outcomes and a reduction in use of other NHS resources, including bed days for mental health providers and in primary care by reducing the costs associated with treating the side effects caused by other antipsychotics, which may become apparent many years after treatment.
- It was noted that DPT already has an internal non-formulary management process in place whereby specialists accessed lurasidone for a limited number of their patients. The specialists present did not feel that use of this process impacted on their clinical choice or was onerous to use. An initial filtering of patients takes place via conversations with relevant people prior to completion of the formal paperwork.
- Currently patient numbers on treatment are small. However, committee members expressed concern that although DPT appeared to have a good system in place for ensuring appropriate use, potentially a large group of patients may be treated with lurasidone in place of alternatives across Devon if it became a routinely commissioned alternative.

The committee voted unanimously against the routine commissioning of lurasidone for schizophrenia. Members cited the need to avoid use where it was possible by choosing better value alternatives and the existence of the individual funding request panel route for cases thought to represent an exceptional combination of factors to the general case.

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

5. Bevacizumab for diabetic macular oedema policy unpublished

The CCGs' commissioning policy on the use of bevacizumab for the treatment of diabetic macular oedema was adopted by the CCGs in Devon on 1st April 2013, having been originally been agreed by the previous commissioning organisations.

The policy states that bevacizumab is NOT routinely commissioned for this indication. However, there are now three drugs which have received recommendations in National Institute for Health and Care Excellence (NICE) technology appraisals. These are now well established in practice and therefore the rationale for the existing policy now lacks clinical relevance.

The Strategic Leadership Committee of the CCGs in Devon has formally acknowledged that the mandatory NICE Technology Appraisals have resulted in changes to clinical practice making the rationale for the existing policy obsolete.

It has been agreed that the policy for bevacuzumab for diabetic macular oedema is unpublished accordingly.

6. Annual Report 2017-18

The committee were asked to receive the fifth annual report of the Clinical Policy Committee (CPC). The annual report sets out the activity of the committee in 2017-18 and the governance and operational arrangements underpinning the meetings.

Through CPC, NEW Devon CCG and South Devon and Torbay CCG discharge their responsibilities for making local decisions about the funding of medicines and treatments collaboratively, ensuring consistency in decision making for patients in Devon.

Over the past year six meetings have been held, these considered fifteen evidence assessments resulting in commissioning recommendations for approval by the CCGs. Three previous decisions have also been updated or unpublished in light of the publication of mandatory NICE technology appraisal guidance.

Engagement with local clinical specialists takes place as part of the assessment process, and they are invited to attend meetings to contribute to discussions.

There have been some membership changes during the year:

Long-standing committee member Dr Mick Braddick stepped down from the committee in March 2018 due to retirement.

The committee are pleased to welcome Dr Nick D'Arcy from May 2018 and Dr Andrew Harrison from July 2018, filling the two voting member vacancies.

Miles Earl will be stepping down from his role as finance representative on the committee.

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 were pleased to welcome Mark Taylor as a new lay public member to the committee from 1 April 2017.

The clinical policy engagement and consultation panel continues to support the CPC and the CCGs by providing a separate opportunity to reflect on the policy recommendations and consider the public interest issues, and 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. 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 (QEIA) 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, submitted to the QEIA authorisation panel for approval, and submitted to the CCGs along with the final policy recommendation for approval.

A committee development session was held in January 2018. This sought to build on the previous development session where it was suggested that it would be helpful to look back at previous decisions made by the committee. The Clinical Effectiveness team undertook work to assess the impact of published commissioning policies which provoked interesting discussion. It was felt a report should be produced to highlighted the themes identified during the discussion and that this should be shared with the CCGs to enhance their understanding of the wider contextual issues around clinical policy development. This report has now been produced.

As a result of the production of the annual report, a desktop exercise has been undertaken by the committee secretariat to ensure that the terms of reference of the group is up-to-date and any necessary changes are identified. This has resulted in updated draft Terms of Reference which it is proposed to submit to the CCGs for acceptance. The updated Terms of Reference were accepted by the committee.

The changes are largely minor for clarity and accuracy of current processes. The declaration of interest section has also been updated to ensure that this explicitly reflects that we operate in accordance with the revised statutory guidance for CCGs on managing conflicts of interest.

CPC received the report as a record of activity in 2017-18. The report will be submitted to the appropriate groups of both NEW Devon CCG and South Devon and Torbay CCG for information and assurance. It will then be published via the website to ensure it is publically 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: Updated Terms of Reference to be submitted to the appropriate bodies of the CCGs to be ratified.

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

7. Update from NICE Planning Advisory Group (NPAG)

The committee received an update from the NICE Planning and Advisory Group meeting which took place on Tuesday 6th March 2018.

NPAG had considered seventeen NICE technology appraisals and one highly specialised technology guidance. The majority of the technology appraisals and the highly specialised technology guidance are commissioned by NHS England.

Other guidelines and guidance considered by NPAG included three public health guidelines, of which two were updated guidelines, one social care guideline, eight clinical guidelines and one interventional procedure.

8. Update from Clinical Policy Engagement and Consultation Panel

The committee received an update from the Clinical Policy Engagement Consultation Panel meeting which took place on 17th April 2018.

Three topics had been discussed:

- Intravitreal Bevacizumab for radiation maculopathy

The panel recommended that no further engagement or formal consultation was required at this point.

- Intravitreal Bevacizumab for rubeosis iridis and neovascular glaucoma

  The panel recommended that no further engagement or formal consultation was required at this point.

- The specialist management of abdominal wall hernia in adults.

  The panel recommended that no further engagement or formal consultation was required at this point. However it was agreed that the existing clinical policy patient support information would be checked to establish whether any updates are required, and that this would be communicated alongside the revised policy.

9. Any Other Business

There was no other business to report.

Summary of actions

	Action	**Lead**
18/01	*FreeStyle Libre device for interstitial glucose monitoring in diabetes: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* *The policy will be published shortly.* The policy has been published. Action complete.	
18/03	*Intravitreal Bevacizumab for radiation maculopathy - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* The policy will be published shortly.	Rebecca Heayn
18/04	*Intravitreal Bevacizumab for rubeosis iridis and neovascular glaucoma - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* The policy will be published shortly.	Rebecca Heayn
18/07	The specialist management of abdominal wall hernia in adults - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication. The policy will be published shortly.	Rebecca Heayn
18/08	Fluticasone furoate and vilanterol trifenatate (Relvar® Ellipta®) combination inhaler for asthma – Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn

18/09	Lurasidone for schizophrenia - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
18/10	CPC annual report to be submitted to the appropriate bodies of the CCGs to be received and ratified.	Rebecca Heayn
18/11	Updated Terms of Reference to be submitted to the appropriate bodies of the CCGs to be ratified.	Rebecca Heayn
18/12	Once ratified CCG annual report to be published and made publically available via the CCG website.	Rebecca Heayn