Northern, Eastern and Western Devon
Clinical Commissioning Group

South Devon and Torbay
Clinical Commissioning Group

Clinical Policy Committee

Minutes

Wednesday 18th July 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
Richard Croker	Head of Medicines Optimisation Northern and Eastern Localities	NEW Devon CCG
Dr Nick D'Arcy	Voting Member	South Devon & Torbay CCG
Paul Foster	Chief Pharmacist	T&SD NHS FT
Dr Andrew Harrison	Voting Member	NEW Devon CCG
Barbara Jones	Head of Locality Contracting	NEW Devon CCG
Mac Merrett	Lay Public Member	
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG
Dr Alison Round	Voting Member	NEW Devon CCG
Mark Taylor	Lay Public Member	
Dr Ben Waterfall	Voting Member	NEW Devon CCG

Guests:

Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Dr William Knight	Consultant Neurologist	Torbay & South Devon NHS FT
Naomi Scott	Healthcare Evidence Reviewer	NEW Devon CCG
Dr Ray Sheridan	Consultant Physician	Royal Devon & Exeter NHS FT
Graham Simpole	Joint Formularies Support 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

1. Welcome and introductions

Apologies

Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Dr Lucy Harris	Voting Member	South Devon & Torbay CCG
Tracey Polak	Assistant Director/ Consultant of Public Health	Devon County Council
Dr Peter Rowe	Consultant Nephrologist	University Hospitals Plymouth NHS Foundation Trust

Richard Croker attended for part of the meeting.

Confirmation of voting members and Declarations of Interest

The seven voting members present were identified.
Dr Lucy Harris had requested Chris Roome to deputise as voting member in her absence.

Declarations of Interest were collected and reported. 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

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Rivaroxaban (Xarelto®) **for the prevention of recurrent deep vein thrombosis and pulmonary embolism**	**Bayer Plc**
Alternative treatments: **Apixaban** (Eliquis®) **Warfarin**	**Bristol-Myers Squibb Pharmaceuticals Ltd** **various manufacturers**
Opicapone (Ongentys®) **for Parkinson's Disease**	**BIAL Pharma UK Ltd**
Alternative treatments: **Entacapone** **Levodopa with carbidopa and entacapone combination products** (Stalevo®, Sastravi®, Stanek®) **Tolcapone** (Tasmar®) **Apomorphine** (APO-go®) **Co-careldopa intestinal gel** (Duopoda®) **Deep brain stimulation**	**various manufacturers** **Orion Pharma (UK) Ltd, Actavis UK Ltd, Teva UK Ltd** **Meda Pharmaceuticals Ltd** **Britannia Pharmaceuticals Ltd** **AbbVie Ltd**

NAME OF ATTENDEE	ROLE	
Rebecca Heayn	Clinical Effectiveness Governance Support Officer	A family member has been diagnosed with Parkinson's disease.
Dr William Knight	Consultant Neurologist	Honorarium for Advisory board participation Bial Pharma 2017. In receipt of transport/hospitality to attend international meeting (EAN2017) Bial Pharma.

Dr Ray Sheridan	Consultant Physician	Principal Investigator for Opicapone drug trial in Exeter - I receive NO funding or salary based on this.

2. Minutes of the meeting held on 23rd May 2018 and matters/actions arising

The minutes of the meeting held on 23rd May 2018 were approved.

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.* This policy has been published. Action complete.	
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.* This policy has been published. 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.* The policy has been communicated with an agreed implementation date of 25 July 2018. Action complete.	
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. The place in therapy for Fluticasone furoate and vilanterol trifenatate (Relvar® Ellipta®) is being discussed by the two Formulary Interface Groups in Devon. Once agreed the policy will be published.	Rebecca Heayn

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

3. Rivaroxaban for the prevention of recurrent deep vein thrombosis (DVT) and pulmonary embolism (PE)

An application has been received for the routine commissioning of 10mg rivaroxaban for the prevention of recurrent DVT and PE in adults who have had a six month course at a therapeutic dose (20mg once daily) and are deemed to be in equipoise regarding their need for continued anticoagulation treatment. The application was submitted by Dr Wayne Thomas, and Dr Tim Nokes, Consultant Haematologists at University Hospitals Plymouth NHS Trust. Naomi Scott, Healthcare Evidence Reviewer, NEW Devon CCG presented an evidence assessment. No specialists were able to attend the meeting.

Venous thromboembolism, or VTE, occurs when a blood clot forms in the deep veins of the leg or pelvis, resulting in DVT, or a PE if the clot travels and blocks a blood vessel in the lungs. To prevent the formation of further clots patients are treated with an anticoagulant. The presentation of a clot is classified as provoked or unprovoked. Patients with a provoked VTE can generally safely discontinue treatment after three to six months. However, where the cause is unprovoked the optimal length of treatment is unknown. The decision to continue treatment is based on the balance of benefit, in the prevention of VTE recurrence, and the risk of bleeding. Following six months of treatment with a 20mg daily dose, rivaroxaban 10mg is licenced for the extended prevention of recurrent DVT and PE. Patients who have a high risk of recurrent DVT or PE should remain on 20mg once daily. The applicants propose that the use of 10mg rivaroxaban is likely to lower the risk of bleeding, compared to 20mg, without increasing the risk of recurrent VTE.

Until the licence for 10mg rivaroxaban was extended, 2.5mg apixaban twice daily was the only novel oral anti-coagulant (NOAC) licenced for secondary prevention of VTE. Currently local patients who are in equipoise following 6 months of anticoagulation would continue their existing dose of medication, or switch to 2.5mg apixaban twice daily.

The efficacy and safety of 10mg and 20mg rivaroxaban in comparison to aspirin in patients who had been previously treated with anticoagulants for 6-12 months was assessed in the Einstein Choice trial. This trial found patients who had been treated with 10mg or 20mg rivaroxaban had a significantly lower occurrence of VTE events than those receiving aspirin. In terms of safety there were no significant differences between the rates of major, or clinically relevant non-major, bleeding with rivaroxaban 10mg or 20mg compared to aspirin. The study was not designed to show non-inferiority of the 10mg rivaroxaban dose in comparison to 20mg. The authors state that

any conclusions with respect to the non-inferiority of 10mg in comparison to 20mg are speculative. Within the Einstein-Choice trial 43% of patients randomised to 10mg rivaroxaban had an unprovoked initial VTE. In contrast, in previous trials of 20mg rivaroxaban and 2.5mg apixaban 73% and 93% of patients respectively in the active treatment arm had an unprovoked initial VTE. Patients whose initial VTE events are unprovoked have been shown to have twice the risk of recurrence in comparison to those with a provoked initial episode. Furthermore, local specialists state that aspirin, the trial comparator, is not considered an appropriate option for the secondary prevention of VTE.

In real terms the consideration after patients have completed 6 months of anticoagulation treatment is whether to continue or cease treatment. These factors combined with the study design limits the ability of these results to provide data of comparative efficacy or safety between the two doses of rivaroxaban.

The use of 10mg instead of 20mg rivaroxaban is cost neutral. TA341 recommends 2.5mg apixaban for long term secondary prevention of DVT and PE. The use of 10mg rivaroxaban in place of 2.5mg apixaban BD is £36.50 cheaper per patient per year. No cost-effectiveness analyses were identified. Given the lack of comparative evidence of 10mg and 20mg rivaroxaban it was not possible to estimate the cost effectiveness of switching equipoise patients to 10mg rivaroxaban.

The committee discussed issues pertinent to this recommendation:

- A number of queries were raised which the committee felt required attendance of specialists at the meeting to resolve. These included clarification of the characteristics of the patients who comprise the equipoise group in the application and the extent to which the available trial data supports effectiveness, the similarity between trial populations and those being seen in practice, recurrence rates.

Other points raised during the discussion included:

- Whether compliance with twice daily apixaban in routine practice is good enough to gain the benefits found in trial settings and whether the once daily regimen of rivaroxaban might be advantageous.
- The limitations of the trial to provide convincing evidence that rivaroxaban 10mg was as effective as 20mg.
- The absence of data comparing long term rivaroxaban with long term warfarin in the patients being considered as warfarin would be the standard in many doctors practice.
- Differences in recurrence rates that are reported in Einstein choice compared to other data sources

The committee agreed that, due to there being a number of unanswered questions requiring specialist input, a decision could not be taken in the absence of specialists. It was agreed that the Committee Chair would write to specialists to inform them that it had not been possible for the committee to make a decision and the reasons for this. The application may be considered at a future meeting subject to the attendance of specialists.

ACTION: **Jo Roberts to write to specialists stating that the committee had been unable to reach a decision in their absence as specific questions were raised during the discussion which required their input. The application may be considered at a future meeting subject to the attendance of specialists.**

4. Opicapone for Parkinson's Disease

An application for the routine commissioning of opicapone for the treatment of Parkinson's Disease has been received from Dr Ray Sheridan. Graham Simpole, Joint Formularies Support Pharmacist, NEW Devon CCG presented an evidence review. Dr Sheridan and Dr William Knight took part in the discussion.

Opicapone is a peripheral, selective and reversible catechol-O-methyltransferase (COMT) inhibitor indicated, at a dose of 50mg once daily, for the treatment of end-of-dose movement fluctuations in Parkinson's disease.

A systematic literature search identified 2 short-term Randomised Controlled Trials (RCT) studies. Both of these compared opicapone to placebo, whilst one of the studies also included entacapone as an active comparator. Both of these studies were continued as open label extension trials for 12 months following completion of the blinded phases. The primary endpoints across both RCT studies support the claim of efficacy of opicapone, demonstrating superiority to placebo and non-inferiority to entacapone in the reduction of total time in the OFF-state and in the increase of total time in the ON-state. A clear dose-response relationship was not established, but a daily dose of 50mg proved to be consistently efficacious. The secondary endpoints focussing on proportional OFF-time and ON-time responders at the end of the double blind period also support opicapone's efficacy. In both studies, in all treatment groups, dyskinesia was the most frequently reported treatment emergent adverse event and was slightly higher for opicapone compared to entacapone. The European Medicines agency concluded in its public assessment report that safety and tolerability of opicapone is generally good and the majority of adverse events are comparable to other COMT inhibitors.

The acquisition cost of opicapone is higher than that of entacapone, the current formulary choice. The main consideration for opicapone is that it would provide an alternative option for patients in whom entacapone has been ineffective or not tolerated. Should opicapone successfully manage this patient group, it may delay the need for progression to the more complex and costly, non-oral therapies; injectable apomorphine, duodopa gel, or Deep Brain Stimulation (DBS) and may therefore be cost saving.

The committee discussed issues pertinent to this recommendation:

- A specialist present indicated involvement in a phase 4 clinical trial and stated that in his experience patients taking opicapone experienced meaningful improvements in their quality of life.
- Opicapone is a new drug. It is a once daily treatment which could have an important place in the treatment ladder before the need to step up to more complex treatments. It can be used at a time when patients are less likely to be able to cope with an increasing drug burden. Specialist opinion also indicated that opicapone may work better than other drugs due to the time of day it is taken. Specialists present also stated that when patients fail on entacapone it is often due to diarrhoea
- Published RCT support the efficacy of opicapone. However these trials were not in patients who had previously failed on entacapone.
- As there was no evidence of response rates in patients failing treatment with entacapone a paper was tabled by the Clinical Effectiveness Team which modelled the treatment response rate required for equivalent cost-efficiency of a 3 month patient trial of opicapone compared to progression straight to apomorphine. The threshold for equivalent cost efficiency was a response rate of 2.5% suggesting that if one out of 39 patients does not need to go on to advanced treatment there could be equivalent cost efficiency. Specialist opinion was that response rates would be higher than this. Specialists acknowledged the potential for prescribing of opicapone to increase. However they also stated that they were responsible prescribers and that the aim was for patients to remain active and engaged and that they

tried to give only as much drug treatment as needed and focus on exercise, diet, bowel function and rest.

- Successful treatment has the potential to reduce or put off the need for patients to require social care in their own home or to be cared for in a residential care home and may result in cost savings. It can also reduce falls, fractures and hidden costs associated with patients who are undertreated.
- The Clinical Effectiveness Team had reviewed prescribing data for Devon, combined products (levodopa/decarboxylase inhibitor/COMT-I) make up about two-thirds of prescribing by volume but it was unclear the number of patients being treated.
- The number of patients who may potentially undergo DBS brain surgery is increasing. As the outcomes of surgery have improved and the side effects have reduced surgeons are increasingly willing to operate on patients up to 80 years of age. However surgery does not improve the non-motor symptoms of Parkinson's Disease and cannot be used on patients with depression. In addition there is a time lag of up to a year while patients wait for surgery.

The committee voted 6 to 1 in favour of recommending the routine commissioning of Opicapone for Parkinson's Disease.

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

5. Update from NICE Planning Advisory Group (NPAG)

The committee received an update from the NICE Planning Advisory Group meeting which had taken place on 1st May 2018.

NPAG had considered ten NICE Technology appraisals, the majority of which were NHS England commissioned.

Other guidelines and guidance considered by NPAG included one social care guideline, one medicines practice guideline, thirteen clinical guidelines, two medical technology guidelines and one interventional procedures guideline.

The Clinical Policy Committee discussed issues pertinent to 'Mental health problems in people with learning disabilities: prevention, assessment and management' (NG54). It was noted that commissioning arrangements should be in place to ensure that all mental health providers across Devon provide a comprehensive service at agreed levels. Difficulties in achieving this where there is cross over between mental health providers and adult social care providers, with the attendant differences in commissioning arrangements, were noted.

6. Update from Clinical Policy Engagement and Consultation Panel

The committee received an update from the Clinical Policy Engagement and Consultation Panel meeting which took place on 6th June 2018

Two topics had been discussed:

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

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

- Lurasidone for schizophrenia

It had been agreed that Simon Polak would be made aware of the content of discussions around learning disabilities and anti-psychotic use. This has been done.

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

The Clinical Effectiveness Governance Manager has produced an annual report for the Clinical Policy Engagement and Consultation Panel. It has been agreed that the groups Terms of Reference would be reviewed to ensure that they remain up to date and reflect any changes in committee structures and the reporting arrangements of the panel.

7. Clinical Policy Engagement and Consultation Panel Annual Report 2017-18

The Committee received the third annual report of the Clinical Policy Engagement and Consultation Panel.

The Clinical Policy Engagement and Consultation Panel exists to support the CCGs in Devon to determine the need for any further engagement or formal public consultation on clinical policy recommendations made by the Clinical Policy Committee. The panel sits within the context of the wider engagement processes of the CCGs.

The panel welcomed Mark Taylor as the new Clinical Policy Committee lay public member from 1 April 2017 and Jon Taylor in February 2018 to support the advisory role fulfilled by Jenny McNeill.

Five meetings were held last year, considering and making recommendations to the CCGs on a total of nine clinical policy recommendations.

On discussion of these recommendations, the panel had been satisfied that the public interest issues had been fully considered and that further engagement or formal public consultation activity would not yield additional insights. However the panel had made some recommendations in relation to specific policy proposals to support the communication and implementation of these across Devon:

- Cryopreservation to preserve fertility - The panel noted that there would be a patient group receiving an ongoing service for which NHS funding would cease at a defined future date depending on their current age. For some this will be entitlement to NHS funding for a longer storage period whilst for others this would now cease sooner than they may have expected.

  It was recommended that patients who currently have cryopreserved material should be informed of the revisions to the policy so that they can understand how this may affect them. The CCGs should engage with the fertility centres in order to identify and communicate with those individuals affected, and this should accompany communication/ publication of the revised policy.

- FreeStyle Libre device for interstitial glucose monitoring in diabetes - The panel felt that due to high levels of interest in the FreeStyle Libre Device from the diabetes community, a letter should be drafted for specialists who run secondary care diabetes clinics clearly explaining the policy position, the reasons for it and where patients can access information on the policy from the CCG.

  This information should also be made available to the CCGs' patient advice and engagement teams to provide the explanation being given to patients who are not eligible for the device due to not meeting the criteria.

Both of these recommendations were agreed and the actions were carried out (following communication with patient advice and experience and communications colleagues) when these policies were published and disseminated.

Clear governance arrangements are in place for the operation of the panel. A register of interests, terms of reference, minutes and meetings arrangements are all made publicly accessible online.

The terms of reference have undergone an annual review to ensure that these remain up to date and reflect any changes in committee structures and the reporting arrangements of the panel. The annual report will be submitted to the CCGs' Engagement Committee for acceptance and assurance as well as being reported to the Clinical Policy Committee for information.

8. Any Other Business

There was no other business to report.

Summary of actions

	Action	**Lead**
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. The place in therapy for Fluticasone furoate and vilanterol trifenatate (Relvar® Ellipta®) is being discussed by the two Formulary Interface Groups in Devon. Once agreed the policy will be published.	Rebecca Heayn
18/13	Rivaroxaban for the prevention of recurrent deep vein thrombosis (DVT) and pulmonary embolism (PE): letter to be written to specialists stating that the committee had been unable to reach a decision in their absence as specific questions were raised during the discussion. The application may be considered at a future meeting subject to the attendance of specialists.	Jo Roberts
18/14	Opicapone for Parkinson's Disease - Policy Recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn