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

Clinical Policy Committee (CPC)
Minutes

Wednesday 22nd October 2014, 9.30 am to 12 noon

Henlake Suite, The Watermark, Ivybridge

Present:

Dr Jo Roberts* (Chair)	GP Clinical Commissioner	South Devon & Torbay CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Jono Broad	Lay Member	
Dr Andrew Craig*	GP Clinical Commissioner	NEW Devon CCG
Paul Foster	Chief Pharmacist	SDHC NHS Foundation Trust
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	SDHC NHS Foundation Trust
Dr Peter Leman*	GP Clinical Commissioner	NEW Devon CCG
Dr Phil Melluish*	GP Clinical Commissioner	South Devon & Torbay CCG
Mac Merrett	Lay Member	
Samantha Morton	Head of Contacting and Procurement	South Devon & Torbay CCG
Chris Roome*	Head of Clinical Effectiveness	NEW Devon CCG
Dr Alison Round*	GP Clinical Commissioner	NEW Devon CCG
Larissa Sullivan	Interface Pharmacist	South Devon & Torbay CCG

Guests:

Dr Elizabeth Adams	Consultant Psychiatrist	Plymouth Community Healthcare
Dr Christine Brown	Consultant Psychiatrist	Devon Partnership NHS Trust
Tina Campbell	Pharmacist/ Associate Director of Medicines Management	Devon Partnership NHS Trust
Steve Cooke	Chief Pharmacist & Controlled Drug Accountable Officer	Plymouth Community Healthcare
Dr Michael Cooper	Consultant Psychiatrist	Plymouth Community Healthcare
Dr Keith Gilhooly	Consultant Psychiatrist	Devon Partnership NHS Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG

In attendance:

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

* Denotes voting members

1. Welcome and announcements

Attendees were welcomed to the meeting. The group introduced themselves to Dr Peter Leman who was attending his first meeting as a GP Clinical Commissioner, replacing Dr Keith Gillespie.

Due to the volume and complexity of the business to be discussed, the meeting had been extended by 30 minutes.

Dr Darunee Whiting had deputised voting to Chris Roome.

Samantha Morton represented the CCGs' contracting departments.

Larissa Sullivan represented Richard Croker.

No Public Health committee member was able to attend the meeting.

No Patient Safety and Quality Committee member was able to attend the meeting.

Andrew Gunatilleke and Paul Foster left the meeting early.

Apologies

Richard Croker	Head of Medicines Optimisation	NEW Devon CCG
Tawfique Daneshmend	Secondary Care Clinician	Royal Devon & Exeter NHS FT
Tracey Polak	Public Health	Devon County Council
Andrew Kingsley	Patient Safety and Quality	NEW Devon CCG
Dr Darunee Whiting	GP Clinical Commissioner	NEW Devon CCG

Confirmation of voting members and Declaration of Interest

The seven voting members present were identified.

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

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Olanzapine (ZypAdhera®) **Risperidone** (Risperdal Consta®) **Aripiprazole** (Abilify®) **Paliperidone** (Xeplion®) Comparator first generation antipsychotics: **Flupentixol** (Depixol®) **Fluphenazine** (Modecate®) **Haloperidol** (Haldol®) **Pipotiazine** (Piportil®) **Zuclopenthixol** (Clopixol®)	**Lilly** **Janssen** **Bristol Myers Squibb** **Janssen** **Lundbeck** **Sanofi** **Janssen** **Sanofi** **Lundbeck**
Tocilizumab (RoActemra®)	**Roche**

NAME OF ATTENDEE	ROLE	
Steve Cooke	Chief Pharmacist	Hospitality received where the drug(s)/devices(s)/intervention(s)/treatments(s) under consideration were discussed by a representative of a drug/manufacturing company/companies. Attended meetings of the South of England Chief Pharmacists in Mental Health Group as follows: • Feb 2014: Included a presentation on Abilify Maintena; meeting sponsored by Lundbeck • Feb 2012: Included a presentation on Xeplion: meeting sponsored by Janssen.

NAME OF ATTENDEE	ROLE	
Mike Cooper	Consultant	In receipt of payment/gift for transport and hospitality to attend national or international meetings: • Conference assistance.
Keith Gilhooly	Consultant	Hospitality received where the drug(s) /devices/intervention(s)/treatments(s) under consideration were discussed by a representative of a drug/manufacturing company/companies. • Sandwiches were provided at a free 1 day conference on ZyoAdhere sponsored by the company.
Larissa Sullivan	Interface pharmacist (Representing Richard Croker)	Any other family or business interests (including personal or family medical conditions) which could be seen as influencing views of the drug(s)/interventional/treatment under consideration. • Married to a member of DPT medicines team.

Notification of Any Other Business (AOB)

No items for discussion under AOB were identified.

2. Minutes of the meeting held on 10th September 2014 and matters/actions arising

The minutes of the meeting held on 10th September 2014 were approved.

Actions from previous minutes:

14/04 *Lisdexamfetamine for ADHD in children and adolescents commissioning policy to be published.*
The policy has been drafted and agreed by the CPC chair. Once it has been ratified by the CCGs governing bodies and taken through the FIGS process the policy will be published.
The policy has now been ratified by the CCGs and will be taken to FIGs.

The policy has now been taken to FIGS and is awaiting shared care.

Action complete

14/13 *Fidaxomicin for Clostridium difficile Infection commissioning policy to be published.*
The policy has been drafted and agreed by the CPC chair and submitted for ratification by the CCGs. Once this is complete the policy will be published.

The policy has been published.

14/14 *Dapoxetine for premature ejaculation commissioning policy to be published.*
The policy has been drafted and agreed by the CPC chair and submitted for ratification by the CCGs. Once this is complete the policy will be published.

The policy has been published.

14/15 *Recommendation and summary of clinical discussion to be taken to CCGs' executive groups who will decide whether to implement the recommendation from NICE taking into account prioritisation of funding. (CG168 Referral for varicose veins)*

A paper is due to be submitted to NEW Devon CCG's Executive Group and South

Devon & Torbay CCG's Commissioning and Finance Committee in November 2014.

14/16 *HP to feedback suggestion to relevant CCG colleagues that referral between GP practices for corticosteroid injections and training of more GPs should be explored.*

Action complete

14/17 *Policy for carpel tunnel syndrome to be published.*

The policy has been published.

Action complete

14/18 *Information of sponsorship to be e-mailed to Rebecca Heayn*

Action complete

3. Legislative Reform (Clinical Commissioning Groups) Order 2014 update

The Committee was advised that the Legislative Reform (Clinical Commissioning Groups) Order 2014 (LRO) came into force on 1st October 2014.

The Legislative Reform Order is a response to an unintended consequence of the National Health Service Act 2006. The existing legislation has allowed CCGs to exercise their commissioning functions jointly, but not specifically by way of a joint decision making body. Until the implementation of the changes to the NHS Act the CCGs in Devon continued to exercise their commissioning functions jointly via the Clinical Policy Committee as a "committee in common". In order to ensure that organisational statutory requirements were met, the administrative process for formally ratifying commissioning policies was undertaken by the individual CCGs' governing bodies. All existing commissioning policies and decisions of the Clinical Policy Committee have been formally ratified by the Governing Bodies of the CCGs as an interim until the proposed changes to the Act were implemented.

From 1st October 2014 commissioning decisions of the Clinical Policy Committee will no longer require formal ratification by the CCGs' Governing Bodies. Future decisions will be published and disseminated as per the Communication Framework. NEW Devon CCG Governing Body and South Devon & Torbay CCG Quality Committee will be notified for information only.

It was noted that with regard to Part 2 business a recommendation is taken to the CCGs Executive Groups for final decision. The process is explained in the Committee's Terms of Reference.

The committee discussed a number of issues pertinent to the financial consequences of its commissioning decisions.

- It was noted that a financial limit for CPC decisions had not been formally communicated by the CCGs.
- The role of the committee is to balance the argument for a therapy against the costs and consequences of not providing it. Some members expressed concern that decisions would be made solely on the basis of their budgetary impact.
- A consensus and agreed process for the group is needed for both the clinical and financial elements. It was agreed that Chris Roome would frame a proposal for e-mail discussion.

ACTION: Proposal to be framed for e-mail discussion.

4. Future meeting dates

CPC meetings have been scheduled until December 2015. Details will be e-mailed to committee members with the additional dates highlighted. The Secretariat is mindful of minimising meeting costs as well as rotating between venues across the CCGs' footprint. Where possible, meetings are

held in NHS facilities or those of Devon County Council, which makes no charge as we are a strategic partner.

ACTION: Details of CPC dates until December 2015 to be e-mailed to committee members with the latest dates highlighted.

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

One NPAG meeting had taken place since the Clinical Policy Committee meeting held on 10th September 2014. The committee received a summary of the NICE guidance discussed.

A question was raised with regard to the checking of providers' responses to NICE guidance. It was confirmed that if there were any doubts regarding providers reported alignment with NICE guidance a request could be made that the treatment be included in the providers audit programme. It was also noted that acute trusts have their own clinical effectiveness teams responsible for NICE to discharge provider's responsibilities for issues relating to NICE and audit.

6. Aspirin for the Prophylaxis of Venous Thromboembolism Following Elective Hip Replacement and Elective Knee Replacement

Aspirin for the prophylaxis of venous thromboembolism following elective hip replacement and elective knee replacement is scheduled to be discussed by CPC under Part 2 business. The committee received a verbal update on current practice across Devon.

A briefing document has been written by the Clinical Effectiveness team and circulated to specialists. Specialists have been invited and have agreed to attend the meeting in December 2014.

7. Second-generation antipsychotic depot injections for schizophrenia

An application has been received from Devon Partnership Trust (DPT) supported by Plymouth Community Healthcare (PCH) requesting inclusion of four depot second generation antipsychotics (SGA) into local formularies as alternatives to depot first generation antipsychotics (FGA) for schizophrenia in adults. The committee were asked to consider the evidence for commissioning the SGAs. Hilary Pearce, Clinical Effectiveness Pharmacist, NEW Devon CCG presented an evidence review. Dr Elizabeth Adams, Steve Cooke and Dr Michael Cooper from PCH and Dr Christine Brown, Tina Campbell and Dr Keith Gilhooly from DPT took part in the discussion.

Antipsychotic drugs are the primary treatment for psychosis and schizophrenia with well-established evidence for their efficacy in treating acute episodes and to prevent relapse. Depot FGAs are routinely commissioned for the following indications (1) patient preference after acute treatment or (2) to avoid covert non-adherence (either intentional or non-intentional). The four SGAs are aripiprazole, olanzapine, paliperidone and risperidone. With the exception of paliperidone, these drugs are routinely commissioned as oral preparations. Patients receiving oral risperidone can switch to depot paliperidone. Differences exist between the depot SGAs in term of licensed indications.

The committee reviewed the evidence for SGA depot injections for schizophrenia. Clinical trial data for the depot preparations is limited. In terms of head to head trials an RCT comparing paliperidone and haloperidol and a poorly conducted trial comparing risperidone with zuclopenthixol in patients with schizophrenia and substance abuse were found. With regard to comparisons between SGAs, there are head to head trials for paliperidone and risperidone but not at doses applicable to clinical practice. Data for the depot formulations shows aripiprazole, olanzapine and risperidone are similar to the oral formulations for key efficacy outcomes. In terms of safety outcomes; aripiprazole has an increased risk of extrapyramidal symptoms for the depot formulation compared with the oral formulation.

Due to limited trial data for the depot formulations, meta-analysis for oral formulations was used as supporting evidence. Findings from the meta-analyses comparing SGAs to FGAs indicate that SGAs have lower risks of relapse, all cause treatment discontinuation and less extrapyramidal symptoms than FGAs. In terms of weight gain, an indicator of metabolic risk, differences were seen

between the antipsychotics; aripiprazole was associated with less weight gain than FGAs and olanzapine was associated with more weight gain. The NICE network meta-analysis shows that aripiprazole and risperidone have similar relapse rates whilst olanzapine and paliperidone have lower relapse rates. NICE state that credible intervals are wide and there is a high degree of uncertainty associated with this model. A similar analysis conducted for RCTs of depot preparations for the aripiprazole submission to the All Wales Medicines Strategy Group (AWMSG) also has very wide credible intervals but suggests similar relapse rates for aripiprazole and risperidone. AWMSG state that it is not possible to reliably determine relative efficacy outcomes from the analysis. The head to head trial between paliperidone and haloperidol suggests an analysis of more recent data might show a higher relapse rate for paliperidone than the NICE analysis.

There is no cost-effectiveness analysis which incorporates all depot second generation antipsychotics, no analysis for depot second generation vs depot first generation and no analysis for depot risperidone. The AWMSG submission for aripiprazole has the most SGA comparators and shows aripiprazole to be dominant to paliperidone and risperidone. Analysis was undertaken for this review using relapse rates, utility data and costs from the NICE economic model for relapse prevention for oral antipsychotics to address cost-effectiveness of all depot second-generation antipsychotics for the circumstances relevant to the commissioning decision. It was found that none of the depot SGAs were cost-effective compared with depot FGAs in the base case or sensitivity analysis. Relapse is associated with significant costs. If depot SGAs are compared to no treatment (proxy for non-compliance) depot SGAs were cost effective during the 1st year. In subsequent years depot SGAs were not cost-effective compared to 'no treatment' in the base case, but in sensitivity analysis where the base case relapse rates were reduced within credible intervals or where different utility data using UK patient data rather than US data were used, aripiprazole, olanzapine, and paliperidone were cost-effective at a willingness to pay threshold of £20,000.

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

- The evidence base – although evidence was limited depot SGAs are similar to oral formulations.
- Clinical freedom and alignment with NICE recommendations.
- The benefits to patients and wider society of depot SGAs such as alignment with oral treatment options, fewer relapses due to non-compliance, different side effect profile than experienced with FGAs, the potential for quicker discharge of appropriate patients from secure units, potential cost savings as a result of patients spending less time in secure units and freeing of inpatient beds reducing the need for out of area placements.
- Benefits of depot SGAs over oral preparations – once stabilised on a depot preparation patients who were previously noncompliant are able to gain an insight to their condition and understand the need to be more compliant with oral therapy. Depot treatment is therefore not necessarily long term. This reduces the costs that are incurred.
- Specialists stated they would only consider depot SGAs for non-compliance or medical factors precluding a depot FGA.

The committee voted 6 to 1 in favour of commissioning the second-generation antipsychotic depot injections aripiprazole, olanzapine and paliperidone for schizophrenia in patients who are non-compliant with antipsychotic medication or where depot FGAs are not clinically appropriate. The committee member voting against commissioning these therapies cited costs and uncertainly over whether the therapy would provide value for money compared to current treatments.

ACTION: Commissioning policies for depot injections of aripiprazole, olanzapine and paliperidone for schizophrenia to be published.

It was noted that CPC discussions were starting to be about affordability. The question of wider attendance at meetings was raised as was the possible need for additional information to be included in the meeting papers. It was felt that further reflection on these issues was needed and that a meeting to include Jo Roberts, Samantha Morton, Chris Roome, Rebecca Heayn and Jono Broad should take place.

ACTION: Meeting to take place regarding contracting elements of CPC decision making.

8. Subcutaneous Tocilizumab for rheumatoid arthritis

An application has been received requesting the inclusion of subcutaneous (sc) tocilizumab in combination with methotrexate for rheumatoid arthritis as an alternative to iv infusion in line with NICE guidance TA247 into local formularies. The committee were asked to consider the evidence. Hilary Pearce, Clinical Effectiveness Pharmacist, NEW Devon CCG presented an evidence review. Written comments had been received from Dr Richard Haigh, Consultant Rheumatologist RD&E and Dr Stuart Kyle Consultant Rheumatologist, NDDH. These were tabled at the meeting.

Tocilizumab is a biological agent licenced for the treatment of rheumatoid arthritis in combination with methotrexate. It has a different mechanism of action to other biological agents licensed for this indication. Use of the sc formulation offers a more convenient method of administration for patients currently receiving tocilizumab than the iv formulation and would increase the range of drugs recommended by NICE available for sc use. The sc formulation is administered weekly. Treatment will be provided by homecare and frees up infusion clinics.

The committee reviewed the evidence for commissioning subcutaneous tocilizumab in combination with methotrexate in patients with rheumatoid arthritis.

Two randomised controlled trials have been published for subcutaneous tocilizumab in combination with methotrexate. The key trial was a comparison of the sc and intravenous (iv) formulations. The study demonstrated non-inferiority of sc tocilizumab to iv tocilizumab. An ACR20 response was achieved by 69.4% of the sc-treated group and 73.4% of the iv-treated group. Comparable outcomes for the two formulations were reported for ACR50, ACR70, disease remission and proportion of patients with a clinically significant change in HAQ-DI score.

Use of the sc formulation of tocilizumab compared with the iv formulation would result in cost savings for the health-care community. Dosing of iv tocilizumab is weight-based therefore the cost of treatment increases with an increase in the weight of patients.

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

- use of this therapy would be cost saving, better for patients, free up resources and clinical time;
- uptake may increase due to easier access and reduce costs;

The committee voted unanimously in favour of commissioning subcutaneous tocilizumab for rheumatoid arthritis.

ACTION: Commissioning policy for subcutaneous tocilizumab for rheumatoid arthritis to be published.

The committee also discussed a number of issues pertinent to the wider role of the committee and decision making process, including:

- Noting that whilst this decision appeared very obvious to take, it was correct to follow due process.
- Work undertaken should be proportionate to the clinical and financial significance of the request.
- Although time consuming for committee members, the process overall saves multiple clinicians across the localities of the CCGs from needing to engage on the detailed considerations relevant to taking a commissioning decision.
- The CPC membership should have a greater role in assigning prioritisation to request, so that the scarce evidence and cost effectiveness review resources are not disproportionately devoted to requests considered to be of low clinical priority.

9. Any other business

There was no other business to report.

Summary of actions		
	Action	**Lead**
14/15	*Recommendation and summary of clinical discussion to be taken to CCGs' executive groups who will decide whether to implement the recommendation from NICE taking into account prioritisation of funding. (CG168 Referral for varicose veins)* A paper is due to be submitted to NEW Devon CCG's Executive Group in November 2014.	Rebecca Heayn
14/19	Proposal to be framed for e-mail discussion to agree process and remit for CPC clinical and financial responsibility.	Chris Roome
14/20	Details of CPC dates until December 2015 to be e-mailed to committee members with the latest dates highlighted.	Fiona Dyroff
14/21	Commissioning policies for depot injections of aripiprazole, olanzapine and paliperidone for schizophrenia to be published.	Rebecca Heayn
14/22	Meeting to be arranged regarding contracting elements of CPC decision making.	Jo Roberts
14/23	Commissioning policy for Subcutaneous Tocilizumab for rheumatoid arthritis to be published.	Rebecca Heayn